**The Impact of Verbal Explanation and Modified Consent Materials on Orthodontic
Informed Consent**

THESIS

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By

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ABSTRACT

Introduction: Previous orthodontic informed consent research shows low patient/parent recall and comprehension of treatment risks and limitations. The purpose of this study was to: 1) evaluate the effectiveness of a shortened oral presentation of an established informed consent method and 2) determine if customized computer-based presentations (PPTs) improve the recall and comprehension of the risks and limitations of orthodontic treatment. **Methods:** Eighty parent/patient pairs were randomly assigned to one of two groups. PPTs were generated for each subject-pair including the most common “core” risk factors (pain, enamel/soft tissue destruction, root resorption, and post-treatment change), up to four patient-specific “custom” risk factors, and other “general” risks and limitations. Group A heard a presentation of the treatment plan and the key points of informed consent. Group B did not hear the verbal explanation of the key points of consent. Subjects in both groups then read the informed consent form, saw the customized PPT, and completed an interview with structured questions, two reading ability tests, and a demographic questionnaire. The interviews were recorded, transcribed, and scored using a previously developed codebook for the percentage of correct recall and comprehension responses. The informed consent issues were assigned to three domains: treatment, risk and responsibility. These groups were compared with patients/parents in the earlier Kang et al study (Group C: modified consent + 18 element

PPT). **Results:** Test-retest reliability for codebook-response rating was $\kappa = 0.86$ and overall subject reliabilities for interview questions for children were $\kappa = 0.30$ and parents $\kappa = 0.42$. There were no significant differences between Groups A, B, or C for any socio-demographic variables. Children in Group A scored significantly higher than Group B for risk recall. They also scored significantly higher than Group C on overall comprehension, risk recall, risk comprehension, and general risks and limitations questions. Children in Group B scored significantly higher than Group C on overall comprehension, treatment recall, and risk recall. Elements resented first in the PPT presentation were recalled and comprehended better than those presented later.

Conclusions: This study suggested little advantage to a verbal review of the informed consent form (other than for patients for the risk domain) when other means of review such as the customized PPT were included. Patients understood best those elements presented first in the informed consent PPT. The findings suggest that the most important information should be presented to patients first and any information provided beyond the first seven points should be given as supplemental take-home material.

Dedicated to my husband, Justin Dugas.

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CHAPTER 1

INTRODUCTION

Literacy is defined as “using printed and written information to function in society, to achieve one’s goals, and to develop one’s knowledge and potential.”¹ In other words, the ability to read and write is a necessity for everyday life in the United States. A person’s success is, in part, defined by it. We are surrounded by tests of literacy daily: reading road signs on the commute to and from work, signing a lease for an apartment, or while reviewing our children’s permission slips for school field trips. All of these documents require the ability to recognize words and sentences and interpret them in order to understand what is being read. Despite efforts in public education, there are individuals in society who lack the ability to perform such tasks. Many professional persons may take the ability to read and write for granted. As a result, common documents are often written at a level beyond basic literacy.¹

In order to maintain health, patients must be able to understand and interpret both verbal and written advice from health care professionals. Drafted by experts in the health professions, health care literature often assumes a higher level of literacy than is possessed by the average patient.²⁻⁵ Brochures and informational pamphlets contain unnecessary technical terms and medical jargon that prevent complete comprehension of conditions and recommendations for treatment. This is further complicated by the fact

that patients are often reluctant to admit when they do not understand the information provided to them and therefore may not ask questions. Moreover, patients may genuinely believe they have a higher level of understanding than what they actually have. These discrepancies in health literacy are considered to be important barriers to treatment of diseases.⁶

Health care decision making has shifted in recent decades from the paternalism of the doctor to the autonomy of the patient.⁷ It is the patient's right to make his/her own decision regarding treatment. It is the doctor's responsibility to ensure the patient is well informed regarding possible risks, benefits, costs and alternatives of his/her treatment decision. Furthermore, it is essential that the health care professional recognize the verbal and nonverbal cues patients give that may indicate they do not understand what they are consenting to. To prevent problems such as litigation after patients elect care, it is of upmost importance that patient education materials be accessible, thorough, and understandable.

Previous studies in medicine and dentistry have concluded that existing educational materials are not sufficient for patients to make a fully informed decision about their care.⁸⁻¹⁰ Other studies have implemented changes that improved understanding during the informed consent process.¹¹⁻¹⁴ The purpose of the proposed study is to compare an established presentation of informed consent to child patients and parents with a more concise presentation as well as to determine if customized informed consent materials with reordered items improve the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment.

COMPREHENSIVE LITERATURE REVIEW

AND

STATEMENT OF THE PROBLEM

The 2003 National Assessment of Adult Literacy (NAAL) estimated that 11 million adults in the United States were non-literate. Some 29% or 63 million adults function at a basic literacy level. The NAAL defined basic literacy as “the ability to perform simple and everyday literacy activities” such as using a TV guide to locate programs showing at a specific date and time. An additional 14% or 30 million adults had the lowest level of literacy, below basic, with “no more than the most simple and concrete literacy skills” such as adding a bank deposit slip or signing a form.¹ With just under half of the U.S. population functioning with limited literacy skills, there was and remains concern regarding how this may affect everyday life including patients’ interactions in the health care system.

The NAAL defined health literacy as “the ability to understand and use health-related printed information in daily activities at home, at work, and in the community to achieve one's goals and to develop one's knowledge and potential.” While health literacy does not translate directly into one’s ability to give health-related informed consent, it does provide a narrower focus to define the difficulties a person might have in reading health related literature. Along with its assessment of basic literacy in 2003, the NAAL

asked its participants to respond to questions regarding health related tasks; for example, to determine the dosage of a medication from a prescription label. It estimated that one-third of adults had less than an intermediate level of health literacy which indicated the inability to read or understand complex documents such as consent forms. These individuals would not be able to use a body mass index chart to describe a healthy weight for someone of a certain height. Only one-quarter of adults with less than a high school education reached the intermediate level of literacy indicating an association between level of education achieved and health literacy.¹⁵ Historically, the majority of tools used to inform and educate patients involve printed material. Dental educational materials have been shown to contain complex medical jargon and verbiage and are often written above the level recommended for patient comprehension.^{4, 5} This is problematic considering most adults have low to intermediate levels of health literacy.¹⁶

In a follow-up study using the NAAL health literacy data, the scores from parent study participants were used to determine how health literacy affected health discrepancies in children. Parents who had a lower than 8th grade education level were eight times as likely to have a low health literacy score while parents who reported limited English skills were 18 times as likely to have a low score. Two-thirds of parents were unable to properly write in names and dates of birth on a health insurance form while the same number of parents could not calculate an annual insurance premium for a specific family size. Lower parental health literacy correlated to increased frequency of children without health insurance coverage and to difficulty understanding and following instructions on over-the-counter medication labels.¹⁷ Lower health literacy in adults has

been linked to poorer overall health of the individual as well as the oral health of their children.^{18, 19} In a review of the pediatric medical literature, DeWalt and Hink found that children of parents with lower health literacy often have worse health outcomes.²⁰

After its own literature review in 1999 conducted by the Council of Scientific Affairs, the American Medical Association (AMA) adopted policies to recognize “limited literacy as a barrier to effective medical diagnosis and treatment” and vowed to help to educate the medical community on the limited literacy status of 25% of its adult population. The AMA also recommended specific programs in medical education aiming to improve communication skills between physicians and patients with low health literacy.²¹ Several studies have been conducted to determine ways to identify patients with limited literacy skills.²² Wallace et al found that the question “How confident are you filling out medical forms by yourself?” helped identify patients with limited or marginal health literacy in 75% of the individuals they surveyed.²³

One study that compared an original surgical informed consent to one modified for greater readability and processability showed improved parent understanding with the modified form.¹¹ Another study showed improved parental understanding of risks and benefits of treatment when pictographs and tables were utilized over standard text presentation. Understanding was especially improved for those parents with limited literacy and numeracy skills.²⁴ Campbell et al studied low-income parents consenting for their children and showed that consent information provided in an enhanced print version (with improved white space, descriptive headings, simplified language and illustrations) was superior to both narrated video tapes or computer-based slideshow presentations.¹²

By contrast, another study that compared a verbal method of informed consent to an audiovisual method found that patients had a greater comprehension in the audiovisual group than the verbal group. Patients with lower education levels had the most benefit for the audiovisual method.¹³

One prescription drug study compared a traditional consent form to a concise informed consent modified to include fewer words, shorter and simpler sentences, and easier readability. The succinct consent reduced the number of pages from fourteen to four. Subjects in both the traditional and concise consent groups scored equally well on a questionnaire designed to measure comprehension of informed consent and the risks and benefits of the study. Subjects were equally satisfied with both consent forms.²⁵

Current methods of informed consent for orthodontic treatment, which may include both written and verbal instructions, are relatively ineffective educational tools as measured by poor recall and comprehension among adolescent patients and their parents.⁹ Both patients and parents often have difficulty remembering specific reasons for treatment, procedures to be expected during treatment, risks of treatment, as well as patient/parent responsibilities during treatment.¹⁰ This low level of comprehension can be linked in part to vocabulary and educational levels of parents, but also is a result of the current methodology of informed consent for dental health care.⁹

In a questionnaire administered to orthodontic patients and parents at least six months after starting treatment, Ernst et al found poor recall scores for risks of treatment. Only 37% of patients responded that they remembered being told of the increased risk tooth decay, 21% remembered the risk of root resorption, 56% the need to wear retainers,

and 35% the length of retention. The authors suggested that consent should be an ongoing process during orthodontic treatment with the practitioner focusing on the risks throughout patient care and at frequent patient adjustment appointments.²⁶

A study comparing written, verbal, and visual methods of orthodontic informed consent demonstrated that none of these methods alone showed a difference in information retention. The authors recommended that the methods be combined to promote the best retention of informed consent materials.²⁷ Kang et al combined improved readability and processability in a modified orthodontic informed consent document (MIC). The MIC reformatted an existing consent document using no higher than 7th grade reading level, less medical jargon, and an active voice. Categorization of key risk elements as well as the balance between text and white space was improved. The authors also developed and validated a novel method for measuring orthodontic informed consent through a patient questionnaire.^{28, 29}

A second phase in the Kang study tested three different methods of orthodontic informed consent using their measurement tool. One group received the informed consent document developed by the American Association of Orthodontists (AAO) while another group received the modified informed consent document (MIC) created by the authors. A third group of subjects received both the MIC and watched a narrated computer-based slideshow that documented the 18 elements found in the modified informed consent document. These elements comprehensively covered a range of risks and limitations of orthodontic treatment. Subjects in the AAO group and MIC group performed with the same level of recall and comprehension. For subjects who received

the MIC document combined with the slideshow, both patients' recall and parents' recall and comprehension improved as compared to either the AAO or MIC form alone.¹⁴

Two limitations Kang's study faced and recognized were the high volume of material presented to the subjects and the duration of the consent process itself. The breadth of information was not in keeping with accepted educational standards which recommend limiting the number of new concepts presented to seven.³⁰

It appears that there are several approaches that could enhance the improved methods of Kang et al by either reducing the presentation length or dealing with the amount of information presented. The length of the informed consent presentation could be addressed by omitting some of the explanation. The lengthy informed consent process in Kang's study included a review of each of the eighteen informed consent elements by the resident's verbal explanation (10-15 minutes in length) and by the patient and parent reading the written consent form (10-15 minutes in length). In addition, the third group in the study viewed an audiovisual slideshow that was 48 slides in length and took approximately ten minutes to view. Despite the fact that the slideshow group had the best overall scores for recall and comprehension, on-target responses only ranged from 44-67%.¹⁴

Research in learning has shown that repetition and review of key points should help subjects better retain the important information in the informed consent. However, it is also possible that multiple reiterations of these key points could overwhelm, confuse the patients and parents or simply fatigue them. These multiple in-depth reviews (verbal, audiovisual, written) span a great deal of time and might inhibit the short term memory

capacity of the subjects, thereby limiting the ability for information to be retained. This could help explain the overall low scores for recall and comprehension in the study by Kang et al. For improved comprehension, it is recommended that new information “get to the point without delay” and in order for it to be committed to long-term memory the information must be “repeated or reviewed”. Seeking a balance between these two concepts appears key to improving recall and comprehension of informed consent materials.³¹

If we accept the position that the current large number of informed consent issues is critical, then this problem also must be addressed. One approach to learning more than seven new concepts at a time is called “chunking”. Placing like items together on a list or in a slideshow may allow the subject to extend his/her short-term memory capacity^{31, 32}.

It is evident that the issues covered by comprehensive informed consent are sizable, and they are also segmented by their likelihood of occurrence and applicability to each patient depending on their condition or treatment plan. For instance, some risks and limitations are experienced by nearly every patient, while others are experienced or a concern with only a smaller subgroup that have more specific problems, like impacted teeth or jaw growth discrepancies. This type of sorting of issues may be an effective way to “chunk” informed consent issues.

The following problems have emerged in the literature as issues a majority of patients are at risk to encounter.

Pain. In one study, 170 adolescent and adult orthodontic patients recorded their pain levels via questionnaires. Within the first 4 hours of orthodontic appliance placement 65% of patients reported experiencing some level of pain. At 24 hours, 94% of all subjects experienced some pain. Intensity of pain was greatest at 24 hours with the average response being a 42 on a scale of 0-100 for pain intensity, which was considered a “relatively moderate” level of pain. After seven days of appliance placement, 25% of patients still reported pain.³³ In another study of 109 adolescents, patients reported some level of pain throughout the 7 day questionnaire period. Eighty-three percent of subjects experienced pain within the first 6 hours with a peak in incidence of 91% and intensity at the 24 hour mark.³⁴ Ngan et al used the visual analog scale to survey 70 patients regarding pain from orthodontic separation and initial arch wire placement. When compared to a control group, patients in the experimental group had increased pain when chewing and biting at 4 hours and 24 hours post separator placement/initial archwire. There was no difference between the control and experimental group at 7 days.³⁵

External root resorption. The majority of patients will experience some level of external root resorption during orthodontic tooth movement. In a study of 400 patients, Taithongchai et al found that 88% of patients experience some measurable amount of radiographic root resorption.³⁶ In a study of 791 consecutive adolescent patients, on average the four maxillary incisors experienced 0.7mm of root resorption while the incisor with the most severe shortening per patient averaged 1.3mm. Patients with a history of incisor trauma showed significantly more root shortening than those who had no trauma.³⁷ From their review of the literature, Killiany et al found that one third of

patients will experience a moderate amount of root resorption (at least 3mm) while Weltman et al's systematic review found that 1-5% of all teeth will experience severe resorption of 4mm or more during treatment.^{38, 39}

Enamel destruction. Orthodontic patients experience a significant increase in the number and severity of enamel opacities post-treatment.⁴⁰ In his review of the literature, Mitchell found the prevalence of white spot lesions to range from 2-96%.⁴¹ In a study of 53 adolescent patients (1414 dental surfaces), with banded molars and all other teeth bonded with metal brackets, enamel demineralization took place on 25% of teeth. Teeth more commonly affected were anterior teeth and premolars. The study also reported that higher clinical attachment levels after treatment correlated with the increased incidence of white spot lesions.⁴² Gorelick et al found that 50% of patients had decalcification on at least one tooth after debonding appliances. Ten and eight-tenths percent of all 2,211 teeth studied had a white spot present. Maxillary incisors followed by mandibular posterior teeth had the highest incidence of white spot lesions after orthodontic treatment. Maxillary lateral incisors had three times the number of white spots as maxillary central incisors.⁴³

Post treatment change. Some degree of post treatment change or relapse is present in the vast majority of orthodontic patients. Research has shown that both arch length and arch widths decrease post-treatment, independent of treatment modality. Alignment of mandibular anterior teeth changes significantly post-treatment and continues to do so for multiple years post-orthodontic treatment.^{44, 45} Relapse is

especially common in patients with remaining growth potential, male patients and patients with more severe pre-treatment malocclusions.⁴⁶

In summary, this review of the literature makes it apparent that these four conditions are extremely prevalent risks or limitations associated with orthodontic treatment: pain, root resorption, enamel destruction, and relapse. The majority of patients will experience some degree of pain or discomfort associated with separator placement, initial archwire placement and orthodontic adjustments thereafter. Orthodontics predisposes every patient to some degree of external root resorption. Orthodontic treatment, combined with inadequate oral hygiene and poor dietary choices, also increases a patient's risk for decalcification and decay. Retention of orthodontic treatment can be a challenge for many patients due to compliance and stability issues. Grouping these risk factors together might improve retention of these concepts in the informed consent. These issues could then be logically chunked together.

Another chunk could be those issues that are specifically applicable to an individual patient due to their diagnosis and treatment plan. A final chunk could be those issues that fall into neither of the two previous categories.

The overall objective of this research is to examine methods to increase the recall and comprehension among adolescent orthodontic patients and their parents in the current climate of generally low health literacy. Orthodontic patients are more likely to have a better, more efficient treatment result with increased treatment compliance.^{9, 47, 48} Treatment compliance can be linked to the level of understanding of the potential treatment outcomes, i.e. informed consent.^{49, 50} Therefore, making an informed decision

about care prior to its initiation will allow the best treatment outcome possible for adolescent orthodontic patients.

Specific Aims

In order to enhance understanding of the most critical elements of orthodontic treatment, a modified informed consent document previously tested by Kang et. al.¹⁴ for improved processability and readability will be used in conjunction with reduced verbal presentation of informed consent and a chunked computer-based slideshow presentation. The slideshow presentation will contain audiovisual content organized by 1) general issues that apply to most patients 2) the most prevalent selected and specific issues all patients are likely to encounter and 3) those most pertinent issues to that specific patient's care,--in that order. This approach will not reduce the issues presented to patients, but attempt to streamline and simplify the consent process. The results of this study will be compared to results of the previous study by Kang et al.¹⁴

Null Hypotheses

H₀₁: There is no significant difference in recall and comprehension when the resident explanation of risks and limitations of treatment is eliminated.

H₀₂: There is no significant difference in recall and comprehension using the chunked PPT presentation versus the original one.

H₀₃: There is no relationship between the scores on the state-anxiety inventory and reading ability tests and orthodontic informed consent recall and comprehension.

H₀₄: There is no relationship between the recall and comprehension of informed consent and socio-demographic characteristics.

References

1. Kutner M, Greenberg E, Jin Y, Boyle B, Hsu Y, Dunleavy E. Literacy in everyday life: Results from the 2003 national assessment of adult literacy. Washington, DC: U.S. Department of Education: National Center for Education Statistics; 2007;NCES 2007–480.
2. Kilbridge KL, Fraser G, Krahn M, et al. Lack of comprehension of common prostate cancer terms in an underserved population. *J Clin Oncol*. 2009;27:2015-21.
3. Jovic-Vranes A, Bjegovic-Mikanovic V, Marinkovic J, Kocev N. Health literacy in a population of primary health-care patients in Belgrade, Serbia. *Int J Public Health*. 2010.
4. Alexander RE. Readability of published dental educational materials. *J Am Dent Assoc*. 2000;131:937-42.
5. Harwood A, Harrison JE. How readable are orthodontic patient information leaflets? *J Orthod*. 2004;31:210,9; discussion 201.
6. National Institute of Dental and Craniofacial Research, National Institute of Health, U.S. Public Health Service, Department of Health and Human Services. The invisible barrier: Literacy and its relationship with oral health. A report of a workgroup sponsored by the national institute of dental and craniofacial research, national institute of health, U.S. public health service, department of health and human services. *J Public Health Dent*. 2005;65:174-82.
7. Ozar D, Sokol D. *Dental Ethics at Chairsides: Professional Principles and Practical Applications*. Washington D.C.: Georgetown University Press; 2002.
8. Chung V, Horowitz AM, Canto MT, Siriphant P. Oral cancer educational materials for the general public: 1998. *J Public Health Dent*. 2000;60:49-52.
9. Baird JF, Kiyak HA. The uninformed orthodontic patient and parent: Treatment outcomes. *Am J Orthod Dentofacial Orthop*. 2003;124:212-5.
10. Mortensen MG, Kiyak HA, Omnell L. Patient and parent understanding of informed consent in orthodontics. *Am J Orthod Dentofacial Orthop*. 2003;124:541-50.

11. Tait AR, Voepel-Lewis T, Malviya S, Philipson SJ. Improving the readability and processability of a pediatric informed consent document: Effects on parents' understanding. *Arch Pediatr Adolesc Med*. 2005;159:347-52.
12. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: A comparison of print, video, and computer-based presentations. *Patient Educ Couns*. 2004;53:205-16.
13. Rossi M, McClellan R, Chou L, Davis K. Informed consent for ankle fracture surgery: Patient comprehension of verbal and videotaped information. *Foot Ankle Int*. 2004;25:756-62.
14. Kang EY, Fields HW, Kiyak A, Beck FM, Firestone AR. Informed consent recall and comprehension in orthodontics: Traditional vs improved readability and processability methods. *Am J Orthod Dentofacial Orthop*. 2009;136:488.e1,13; discussion 488-9.
15. Kutner M, Greenberg E, Jin Y, Paulsen C. The health literacy of America's adults: Results from the 2003 national assessment of adult literacy (NCES 2006-483). Washington, DC: U.S.Department of Education: National Center for Education; 2006.
16. Kutner M, Greenberg E, Baer J. A first look at the literacy of America's adults in the 21st century. Washington, D.C.: U.S. Department of Education. National Center for Education Statistics; 2006;NCES 2006-470.
17. Yin HS, Johnson M, Mendelsohn AL, Abrams MA, Sanders LM, Dreyer BP. The health literacy of parents in the united states: A nationally representative study. *Pediatrics*. 2009;124 Suppl 3:S289-98.
18. Easton P, Entwistle VA, Williams B. Health in the 'hidden population' of people with low literacy. A systematic review of the literature. *BMC Public Health*. 2010;10:459.
19. Miller E, Lee JY, DeWalt DA, Vann WF,Jr. Impact of caregiver literacy on children's oral health outcomes. *Pediatrics*. 2010;126:107-14.
20. DeWalt DA, Hink A. Health literacy and child health outcomes: A systematic review of the literature. *Pediatrics*. 2009;124 Suppl 3:S265-74.
21. Health literacy: Report of the council on scientific affairs. ad hoc committee on health literacy for the council on scientific affairs, American Medical Association. *JAMA*. 1999;281:552-7.
22. Powers BJ, Trinh JV, Bosworth HB. Can this patient read and understand written health information? *JAMA*. 2010;304:76-84.

23. Wallace LS, Rogers ES, Roskos SE, Holiday DB, Weiss BD. Brief report: Screening items to identify patients with limited health literacy skills. *J Gen Intern Med*. 2006;21:874-7.
24. Tait AR, Voepel-Lewis T, Zikmund-Fisher BJ, Fagerlin A. The effect of format on parents' understanding of the risks and benefits of clinical research: A comparison between text, tables, and graphics. *J Health Commun*. 2010;15:487-501.
25. Stunkel L, Benson M, McLellan L, et al. Comprehension and informed consent: Assessing the effect of a short consent form. *IRB*. 2010;32:1-9.
26. Ernst S, Elliot T, Patel A, et al. Consent to orthodontic treatment--is it working? *Br Dent J*. 2007;202:E25; discussion 616-7.
27. Thomson AM, Cunningham SJ, Hunt NP. A comparison of information retention at an initial orthodontic consultation. *Eur J Orthod*. 2001;23:169-78.
28. Kang EY, Fulks D, Fields HW, Beck FM, Kiyak HA, Firestone AR, Pope A. Pilot study: Developing a tool to measure orthodontic informed consent. *J Dent Res*. 2007;86:1675.
29. Kang EY, Pope A, Fields HW, et al. Clinical pilot study: Validating an orthodontic informed consent measurement tool. *J Dent Res*. 2007;86:1674.
30. Ley P. Memory for medical information. *Br J Soc Clin Psychol*. 1979;18:245-55.
31. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills*. 2nd Edition ed. Philadelphia, PA: J.B. Lippencott Co.; 1996.
32. Doak LG, Doak CC. Patient comprehension profiles: Recent findings and strategies. *Patient Couns Health Educ*. 1980;2:101-6.
33. Scheurer PA, Firestone AR, Burgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod*. 1996;18:349-57.
34. Erdinc AM, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod*. 2004;26:79-85.
35. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop*. 1989;96:47-53.
36. Taithongchai R, Sookkorn K, Killiany DM. Facial and dentoalveolar structure and the prediction of apical root shortening. *Am J Orthod Dentofacial Orthop*. 1996;110:296-302.

37. Linge BO, Linge L. Apical root resorption in upper anterior teeth. *Eur J Orthod.* 1983;5:173-83.
38. Killiany DM. Root resorption caused by orthodontic treatment: An evidence-based review of literature. *Semin Orthod.* 1999;5:128-33.
39. Weltman B, Vig KW, Fields HW, Shanker S, Kaizar EE. Root resorption associated with orthodontic tooth movement: A systematic review. *Am J Orthod Dentofacial Orthop.* 2010;137:462,76; discussion 12A.
40. Mizrahi E. Enamel demineralization following orthodontic treatment. *Am J Orthod.* 1982;82:62-7.
41. Mitchell L. Decalcification during orthodontic treatment with fixed appliances--an overview. *Br J Orthod.* 1992;19:199-205.
42. Lovrov S, Hertrich K, Hirschfelder U. Enamel demineralization during fixed orthodontic treatment - incidence and correlation to various oral-hygiene parameters. *J Orofac Orthop.* 2007;68:353-63.
43. Gorelick L, Geiger AM, Gwinnett AJ. Incidence of white spot formation after bonding and banding. *Am J Orthod.* 1982;81:93-8.
44. Little RM. Stability and relapse of mandibular anterior alignment: University of Washington studies. *Semin Orthod.* 1999;5:191-204.
45. Bondemark L, Holm AK, Hansen K, et al. Long-term stability of orthodontic treatment and patient satisfaction. A systematic review. *Angle Orthod.* 2007;77:181-91.
46. Ormiston JP, Huang GJ, Little RM, Decker JD, Seuk GD. Retrospective analysis of long-term stable and unstable orthodontic treatment outcomes. *Am J Orthod Dentofacial Orthop.* 2005;128:568,74; quiz 669.
47. Beckwith FR, Ackerman RJ, Jr, Cobb CM, Tira DE. An evaluation of factors affecting duration of orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1999;115:439-47.
48. Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of class II malocclusion. *Am J Orthod Dentofacial Orthop.* 2002;121:9-17.
49. Klein A. Informed consent: A practical approach. *Risk Manage Rep.* 1988;1:1-3.
50. Weiner MF, Lovitt R. An examination of patients' understanding of information from health care providers. *Hosp Community Psychiatry.* 1984;35:619-20.

CHAPTER 2

MATERIALS AND METHODS

This study examines the informed consent process and attempts to gauge understanding. It is a comparison of two groups of patients and parents and will be compared to previous research on informed consent. One group (Group A) will be provided a verbal review of their treatment and the risks of orthodontic treatment, read the Modified Informed Consent (MIC), which is a comprehensive document with improved readability, and view a custom “chunked” computer-based slideshow presentation illustrating the informed consent points grouped by those that are common, then those that are highly likely and finally those specific to the patient. The other group (Group B) will have the same information without the verbal presentation of the risks of orthodontic treatment.

Human subject approval

The research protocol was reviewed and approved by The Ohio State University Institutional Review Board (IRB). All subjects couplets (child or adolescent patient and parent) enrolled in this research study completed the HIPAA authorization form, Consent, Assent, and Parental permission forms.

Modified informed consent document

The modified informed consent document (MIC) was developed by Kang et al¹ using the informed consent document for a major university orthodontic clinic and the American Association of Orthodontists Informed Consent for the Orthodontic Patient[®] document (AAO[®]) as a template. The MIC incorporated 18 common elements found in both the COD and AAO forms. These 18 elements were:

1. Cavities, decalcification, gum disease
2. Discomfort
3. Injury from braces and injury from headgear
4. Health updates
5. Tobacco product use
6. Treatment time
7. Retainers
8. Impacted teeth and unerupted teeth
9. Root resorption
10. Large fillings and injured teeth that may need root canal therapy
11. Accidental injury during adjustment appointments
12. Abnormal jaw growth
13. Extractions and orthognathic surgery for severe crowding and mismatched jaws
14. Temporomandibular Joint Disorders
15. Tooth reshaping, interproximal reduction
16. Ceramic appliances and damage to enamel

17. Wisdom teeth

18. Allergies to orthodontic appliances

The MIC contained less medical/dental terminology, utilized an active voice, larger font size, and balanced white space.² The eighteen elements were divided into 1) preventable risks and 2) possible limitations of treatment. Each risk was followed by a recommended action for preventing that risk. Reading grade level of the MIC was determined to be 7th grade by the Fry Readability Formula.¹

Development of the computer-based slideshow

The original PowerPoint (2003, Microsoft Corporation, Redmond, WA) slideshow (PPT) created by Kang et al¹ provided audio and visual cues reviewing the 18 elements of informed consent found in the MIC. For this study, these eighteen elements were divided into three portions, or “chunks”. The chunks were 1) The four most common “core” risks associated with orthodontic treatment as discussed in the literature review: pain, external root resorption, enamel destruction, and post-treatment change, 2) up to four “custom” risk factors that applied specifically to each patient subject (selected by the orthodontist) and 3) the remaining “general” risk factors. The original slideshow was reorganized such that the flow was from the more general to the specific. The slides describing the core and custom risk factors were placed at the end of the presentation. The subjects were unaware of this arrangement and no attention was drawn to the importance or significance of the elements.

Measurement tool for informed consent

The measurement tool utilized a series of open-ended questions that focused on the eighteen elements of informed consent found in the AAO/MIC documents.^{3, 4} The open-ended nature of the questions sought to assess recall and comprehension rather than memorization of informed consent.⁵ Within the interview sequence there were four rephrased recall questions aimed to test for internal reliability of subjects. Scenario-based questions measured subject comprehension by presenting a situation and asking the subject how he/she would manage that particular situation.

Interviewer training

All research assistants carrying out human subject research were CITI (Collaborative IRB training initiative) trained and IRB approved. Research assistants were trained on research protocol, subject recruitment, the consent process and the interview procedure. Interviewing was conducted using a script that incorporated the measurement tool. Interviewers repeated and rephrased questions from the measurement tool as necessary. Interviewers encouraged subjects to answer all questions without leading their response.

Interview recording, subject identification and interview transcription

All subject interviews were recorded using a digital voice recorder. Subjects were identified using a research ID that incorporated the intervention group, subject number (in order of recruitment) and participant type. “A” identified intervention Group A

participants, “B” identified intervention Group B participants, “C” identified child participants, and “P” identified parent participants. All participant information was kept confidential and all identifiers removed. After initial recruitment, subjects were identified only by their research ID.

Digital recordings of the interviews were converted to WAV files using the recorders’ software and transcribed verbatim into a Microsoft® Word document.

Reading ability tests

The reading test portion of the Wide Range Achievement Test 3 (WRAT 3) (Wide Range in cooperation with PAR, Lutz, FL)⁶ and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Terry Davis, Louisiana State University Medical Center, Shreveport, LA)⁷ were used to gauge overall reading ability and the health literacy reading ability of both patient and parent subjects. It should be noted that a new test, the REALD-99[®] (Rapid Estimate of Adult Literacy in Dentistry)⁸ has since become available but is still relatively new and underutilized. To maintain consistency between this study and the previous study by Kang¹, REALM was used to assess medical literacy of the subjects.

The WRAT3 measures a subject’s general reading ability and covers ages 5-75. Subjects are asked to read aloud from a list of 42 words.⁶ If a subject is not able to correctly pronounce the first five words, he/she is then asked to read the letter portion of the test. After ten consecutive mispronunciations the test is stopped. The number of

letters and words correctly pronounced is summed and then correlated to an age-matched grade level. The test takes 5-10 minutes to complete.

The REALM test correlates a reader's ability to correctly pronounce health-related words to a health literacy level.⁷ This tool was developed for adults, but was administered to the child subjects as well because, to date, no health literacy test exists for children. Each subject was given 5 seconds to read each word from a list of 66 words with the total list taking about 3 minutes to complete. The number of words correctly pronounced was added and then correlated to a health literacy grade level that ranges from below 3rd grade to high school.

Self-administered questionnaire

A self-administered questionnaire gathered socio-demographic information and state anxiety level. Questionnaires were completed at the conclusion of the reading tests and contained the following sections:

1. Socio-demographic information regarding the subjects' age, gender, yearly income, highest educational grade level completed, work status, dentally related employment, ethnic identity, and previous orthodontic treatment.
2. Self assessment of the subjects' understanding of the risks, benefits, and limitations of orthodontic treatment on a visual analog scale (VAS) anchored at 0 and 10.
3. A six-item Spielberger State-Trait Anxiety Inventory (STAI)⁹ measured state-anxiety of each subject.

Sample size, subject allocation by group

Subjects who were new patients planned for comprehensive treatment at a university graduate orthodontic clinic were recruited by staff and orthodontists at the time of orthodontic records or via a telephone call prior to their consultation. Power analysis based on data from the previous study by Kang et al¹ with a non-directional $\alpha = 0.05$, and a $sd = 19$ indicated a sample size of 40 per group plus a 10% drop out factor would be appropriate to yield a power of 0.82.

Inclusion criteria for subject recruitment in this study were as follows:

- Patients were at least 12 years old (approximately in the 7th grade) and not older than 18 years of age with no previous history of orthodontic treatment
- Patient accompanied by a parent or guardian who could consent for research and treatment and had legal guardianship for at least one year
- Patient and parent did not have any developmental disabilities or urgent medical conditions
- Patient and parent were able to communicate in English
- Patient did not have a sibling or other immediate relative that is currently being treated or has previously been treated at the clinic in the past five years

Two informed consent communication methods were used. Subjects were randomly assigned to the two intervention groups. All scripts for invitation to participate in research, interview scripts, and questionnaires are in the Appendix.

Treatment Group A: resident review of MIC + custom “chunked” computer-based slideshow. The resident explained the treatment process to the patient as well as the alternative treatment options. The resident also verbally reviewed the elements of the Modified Informed Consent document. The patient then read the Modified Informed Consent document and viewed the customized “chunked” computer-based presentation.

Treatment Group B: custom “chunked” computer-based slideshow. The resident provided an explanation of treatment and alternative treatment options. The patient read the Modified Informed Consent document and viewed the customized “chunked” computer-based presentation.

These groups allowed comparisons to each other to determine the effect of the verbal presentation of the treatment risks and limitations and allowed comparison to the Kang et al¹ data to determine the effect of the customized “chunked” computer-based slideshow to the standard computer-based presentation. Both variations in the current protocol were designed to reduce the complexity of the amount of information provided.

Orthodontic case presentation/consultation

The following information regarding the patient’s treatment was reviewed with both the patient and parent during the consultation:

- The reasons for the recommended orthodontic treatment (the patient’s orthodontic problem list and diagnosis)
- The proposed orthodontic treatment plan

- Alternative treatment plans, including the option of not having treatment
- The type of orthodontic treatment (fixed appliances, removable appliances, clear aligners, functional appliance, surgical)
- The estimated length of treatment time
- The main points of the treatment informed consent were reviewed (Group A only)

Sequence of the study

- 1) Patient and parent assented/consented to the study with a research assistant.
- 2) For Group A, orthodontic resident reviewed treatment plan, options and risks and limitations of treatment found on the modified informed consent document (MIC) with the patient and parent.

For Group B, orthodontic resident reviewed treatment plan and treatment options only with the patient and parent.

- 3) Patient and parent review MIC on their own (10-15 minutes)
- 4) Resident answered questions and obtains parent/guardian signatures on MIC if parent agrees to the proposed treatment as well as its risks, benefits and limitations.
- 5) Resident completed clinical appointment (e.g. places separators) after which both patient and parent return to the consult area to complete the remainder of the study.
- 6) Research assistants started the computer-based slideshow presentation for patient and parent on separate computers in separate consult rooms.
- 7) Patient and parent were independently interviewed by the research assistants.

Interviews were tape recorded.

- 8) Research assistants conducted the REALM[®] and the WRAT 3[®] for both patient and parent independently.
- 9) Patient and parent completed the self-administered questionnaire with optional demographic questions.
- 10) Children were compensated for their participation in the study.

Scoring of interview responses

A previously developed codebook identified key words or phrases signifying recall and comprehension of the eighteen elements of informed consent.¹ The response rater reviewed and gained proficiency using the codebook with its authors prior to scoring the interviews for this study. Using the codebook, transcribed interviews were reviewed and the responses were scored as either 1) inappropriate 2) on-target (correct) 3) "I don't know/cannot remember" 4) question skipped/ no response given. As more interviews were scored, additional acceptable responses were identified and added to the codebook.

Internal reliability

Four concepts within the recall portion of the measurement tool were rephrased to test internal reliability of the patient and parent subjects. The elements that were repeated were health updates, retainers, TMD, and unerupted/impacted teeth. A simple kappa statistic with 95% confidence interval was used to determine reliability of the subject.

Reproducibility

The response rater's inter-rater reliability was evaluated by scoring 10 patient and 10 parent interviews chosen at random from the previous data set from Kang et al¹ and compared to the scores of that study's response rater. Two weeks after their original scoring, the response rater rescored 10 patient and 10 parent interviews from this study's data set to evaluate intra-rater reliability. Simple Kappa statistics with 95% confidence intervals were calculated for the inter-rater and intra-rater reliability.

Comparisons made in this study

Between Groups A and B. This will evaluate the outcome of eliminating the verbal explanation of the informed consent issues and benefit of shortening the presentation.

Between Group B and C (Kang et al¹). Data from a historical treatment group, Group C, was used to assess the customization of the computer-based slideshow. In the Kang et al¹ study this third group of subjects reviewed the main points of the treatment informed consent with their resident, reviewed the MIC on their own and watched a narrated computer-based slideshow that documented the 18 elements found in the modified informed consent document. All subjects from group C watched an identical computer-based slideshow.

Data analysis

All data were entered into Microsoft® Office Excel workbooks and analyzed using statistical software (SAS). Responses coded as “on target” counted toward percentage correct responses. Responses coded as “inappropriate”, “don’t know/can’t remember” and “question skipped/no response” counted toward percentage incorrect responses. All “question skipped/no response” responses were counted as missing data.

Simple Kappa statistics with 95% confidence intervals were calculated for the inter-rater (Kang et al¹ vs. present study) and intra-rater reliability as well as subject reliability. Descriptive statistics were used to analyze socio-demographic data, REALM scores, WRAT 3 scores, STAI-6 scores, and VAS self-assessment scores. Analysis of variance (ANOVA), Kruskal-Wallis, Chi-square, and Fisher exact tests were used to analyze the distribution of any potential confounding socio-demographic variables within the groups. Spearman correlation coefficients with Bonferroni corrections were used to calculate the correlations between mean percentage of on-target responses, REALM scores, WRAT 3 scores, STAI-6 scores, and VAS self-assessment scores. Data from the present study was combined with that from the Kang et al¹ for analysis. An ANOVA and Tukey-Kramer procedure were used to evaluate the following differences between Groups A, B and Group C (the Kang et al¹ study): mean percentage of on-target responses for overall recall questions and comprehension questions; the domains of treatment, risk, and responsibility; and the core, custom, and general elements of the slideshow. The level of significant difference was set at $\alpha = 0.05$.

To further investigate the effect of ordering and determine whether the serial positioning effect¹⁰⁻¹³ was present for Groups A and B, a second order polynomial regression was applied to the percentage correct responses that were aligned with the order of the concepts in the slideshow presentation. Previous authors Murdock¹⁴ and Bonk¹⁵ analyzed their serial positioning data using curvilinear functions. An ANOVA procedure was used to evaluate the level of significance of the regression.

References

1. Kang EY, Fields HW, Kiyak A, Beck FM, Firestone AR. Informed consent recall and comprehension in orthodontics: Traditional vs improved readability and processability methods. *Am J Orthod Dentofacial Orthop.* 2009;136:488.e1,13; discussion 488-9.
2. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills.* 2nd Edition ed. Philadelphia, PA: J.B. Lippencott Co.; 1996.
3. Kang EY, Fulks D, Fields HW, Beck FM, Kiyak HA, Firestone AR, Pope A. Pilot study: Developing a tool to measure orthodontic informed consent. *J Dent Res.* 2007;86:1675.
4. Kang EY, Pope A, Fields HW, et al. Clinical pilot study: Validating an orthodontic informed consent measurement tool. *J Dent Res.* 2007;86:1674.
5. Hochhauser M. Informed consent and patient's rights documents: A right, a rite, or a rewrite? *Ethics Behav.* 1999;9:1-20.
6. *Wide Range Achievement Test (WRAT 3).* Wilmington, DE: Wide Range Inc.; 1993.
7. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Fam Med.* 1993;25:391-5.
8. Richman JA, Lee JY, Rozier RG, Gong DA, Pahel BT, Vann WF, Jr. Evaluation of a word recognition instrument to test health literacy in dentistry: The REALD-99. *J Public Health Dent.* 2007;67:99-104.

9. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the spielberger state-trait anxiety inventory (STAI). *Br J Clin Psychol.* 1992;31 (Pt 3):301-6.
10. Atkinson RC, Shiffrin RM. The control of short-term memory. *Sci Am.* 1971;225:82-90.
11. Bhatarah P, Ward G, Tan L. Examining the relationship between free recall and immediate serial recall: The serial nature of recall and the effect of test expectancy. *Mem Cognit.* 2008;36:20-34.
12. Bousfield WA, Whitmarsh GA, Esterson J. Serial position effects and the marbe effect in the free recall of meaningful words. *J Gen Psychol.* 1958;59:255-62.
13. Gershberg FB, Shimamura AP. Serial position effects in implicit and explicit tests of memory. *J Exp Psychol Learn Mem Cogn.* 1994;20:1370-8.
14. Murdock BB,Jr. The distinctiveness of stimuli. *Psychol Rev.* 1960;67:16-31.
15. Bonk WJ, Healy AF. Learning and memory for sequences of pictures, words, and spatial locations: An exploration of serial position effects. *Am J Psychol.* 2010;123:137-68.

CHAPTER 3

MANUSCRIPT:

The Impact of Verbal Explanation and Modified Consent Materials on Orthodontic Informed Consent

ABSTRACT

Introduction: Previous orthodontic informed consent research shows low patient/parent recall and comprehension of treatment risks and limitations. The purpose of this study was to: 1) evaluate the effectiveness of a shortened oral presentation of an established informed consent method and 2) determine if customized computer-based presentations (PPTs) improve the recall and comprehension of the risks and limitations of orthodontic treatment. **Methods:** Eighty parent/patient pairs were randomly assigned to one of two groups. PPTs were generated for each subject-pair including the most common “core” risk factors (pain, enamel/soft tissue destruction, root resorption, and post-treatment change), up to four patient-specific “custom” risk factors, and other “general” risks and limitations. Group A heard a presentation of the treatment plan and the key points of informed consent. Group B did not hear the verbal explanation of the key points of consent. Subjects in both groups then read the informed consent form, saw the customized PPT, and completed an interview with structured questions, two reading ability tests, and a demographic questionnaire. The interviews were recorded,

transcribed, and scored using a previously developed codebook for the percentage of correct recall and comprehension responses. The informed consent issues were assigned to three domains: treatment, risk and responsibility. These groups were compared with patients/parents in the earlier Kang et al¹ study (Group C: modified consent + 18 element PPT). **Results:** Test-retest reliability for codebook-response rating was $\kappa = 0.86$ and overall subject reliabilities for interview questions for children were $\kappa = 0.30$ and parents $\kappa = 0.42$. There were no significant differences between Groups A, B, or C for any socio-demographic variables. Children in Group A scored significantly higher than Group B for risk recall. They also scored significantly higher than Group C on overall comprehension, risk recall, risk comprehension, and general risks and limitations questions. Children in Group B scored significantly higher than Group C on overall comprehension, treatment recall, and risk recall. Elements presented first in the PPT presentation were recalled and comprehended better than those presented later.

Conclusions: This study suggested little advantage to a verbal review of the informed consent form (other than for patients for the risk domain) when other means of review such as the customized PPT were included. Patients understood best those elements presented first in the informed consent PPT. The findings suggest that the most important information should be presented to patients first and any information provided beyond the first seven points should be given as supplemental take-home material.

INTRODUCTION

In 2003, the National Assessment of Adult Literacy (NAAL) defined health literacy as “the ability to understand and use health-related printed information in daily activities at home, at work, and in the community to achieve one's goals and to develop one's knowledge and potential.”² Results from the NAAL revealed low to intermediate health literacy in the U.S. Lower health literacy in adults has been linked to poorer overall and oral health of the individual and of his/her children.³⁻⁵

A practitioner is responsible for ensuring that parents, who are the responsible party when consenting for any health procedure for their child, are well informed regarding possible risks, benefits, costs, and alternatives of the child's treatment. To prevent problems such as litigation after electing treatment, it is important that education materials be accessible, thorough, and understandable. Yet most health education and consent documents are complex and difficult for patients to understand.^{6,7}

Many investigators have sought to improve medical consent procedures to increase patient understanding.⁸⁻¹⁰ The approaches are varied and so are the results. Campbell et al studied low-income parents consenting for their children and showed that consent information provided in an enhanced print version (with improved white space, descriptive headings, simplified language, and illustrations) was superior to both narrated videotapes or computer-based slideshow presentations.⁹ By contrast, another study that compared a verbal method of informed consent to an audiovisual method found that adult patients in the audiovisual group comprehended more than those in the verbal group.

Patients in this study with lower education levels benefited most from the audiovisual method.¹⁰

Current methods of informed consent for orthodontic treatment, which may include both written and verbal instructions, are relatively ineffective educational tools as measured by poor recall and comprehension among adolescent patients and their parents.^{11, 12} Orthodontic informed consent research has shown both patients and parents often have difficulty remembering specific reasons for treatment, procedures to be expected during treatment, risks of treatment, as well as patient/parent responsibilities during treatment.^{1, 11, 12} Ernst et al found poor recall scores for risks of treatment, need for retainers, and length of retention period.¹³

In a study by Kang et al that used a modified consent form combined with a slideshow (a method with improved readability and processability), subjects had better recall and comprehension as compared to a standard or modified consent form alone. However, correct responses only ranged from 44% to 67%.¹

Two limitations current informed consent methodologies face are the large amount of information presented to the patients and the duration of the consent process itself.¹ Research in learning has shown that repetition and review of key points can help subjects better retain the important information in the informed consent.^{14, 15} However, it is also possible that multiple reiterations of key points can overwhelm and confuse the patients and parents or simply fatigue them.^{14, 15}

There are several approaches that could further improve these newer, modified methods. These include either reducing the presentation length or addressing the amount

of information presented. The length of the informed consent presentation can be addressed by omitting some of the explanation. Concise medical consent forms that included fewer words, shorter and simpler sentences, and easier readability did not limit patient understanding.¹⁶ “Chunking”, or placing like items together on a list or in a slideshow also may allow subjects to retain more than seven new concepts in their short-term memory.^{14, 15}

The purpose of this study was twofold: 1) to compare an established, improved presentation of informed consent with a more concise presentation using the same informed consent document, and 2) to determine if customized informed consent audiovisual materials with reordered items in the supporting computer-based slideshow presentation can improve recall and comprehension of the risks and limitations related to orthodontic treatment.

MATERIALS AND METHODS

The research protocol was reviewed and approved by the Institutional Review Board (IRB).

New patients planned for comprehensive treatment at a university graduate orthodontic clinic were recruited to be subjects in this study by staff and orthodontists at the time of orthodontic records or via a telephone call prior to their consultation. Power analysis based on data from the previous study by Kang et al¹ with a non-directional $\alpha = 0.05$, and $sd = 19$ indicated a sample size of 40 per group plus a 10% drop out factor would be appropriate to yield a power of 0.82. A total of 88 patient/parent pairs

agreed to participate in the study. The final sample was comprised of 80 patient/parent pairs due to eight withdrawals based on unanticipated language issues, an unrevealed learning disability, and discovery that subjects had undergone previous orthodontic treatment.

Subjects were randomly assigned to the two intervention groups. All patients met the following inclusion criteria: 12 to 18 years of age, no previous history of orthodontic treatment and no sibling or other immediate relative who had previously been treated at the clinic. Patients and parents were able to communicate in English and did not have any developmental disabilities or urgent medical conditions. All patients were accompanied by a parent or guardian who could consent for research and treatment and had legal guardianship for at least one year. These 40 patient/parent pairs in Group A and 40 in Group B were similar to each other and to the patient/parent pairs in the Kang et al study¹ in terms of demographics, orthodontic history, and health. The third group in the Kang et al¹ study, Group C, to which Groups A and B in this study were compared, included 30 patient/parent pairs. Therefore the final combined sample consisted of 40 patient/parent pairs for each of the Groups A and B and 30 patient/parent pairs for Group C.

For this study, the modified informed consent document (MIC) integrating eighteen elements of informed consent (Figure 1) created by Kang et al¹ was utilized. The MIC contained less medical/dental terminology, utilized an active voice, larger font size and balanced white space (Figure 2).¹⁴ The eighteen elements were divided into 1)

preventable risks and 2) possible limitations of treatment. Each risk was followed by a recommended action for preventing that risk.

The original PowerPoint (2003, Microsoft Corporation, Redmond, WA) slideshow (PPT) created by Kang et al¹ provided audio and visual cues reviewing the eighteen elements of informed consent found in the MIC. For this study, these eighteen elements were divided into three portions, or “chunks”. The chunks were: 1) The four most common “core” risks associated with orthodontic treatment: pain¹⁷⁻¹⁹, external root resorption²⁰⁻²³, enamel/soft tissue destruction²⁴⁻²⁷, and post-treatment change²⁸⁻³⁰ as supported in the literature, 2) up to four “custom” risk factors that applied specifically to each patient subject (selected by the orthodontist) and 3) the remaining “general” risk factors. The original slideshow was reorganized such that the flow was from the more general to the specific. The slides describing the core and custom risk factors were placed at the end of the presentation. The subjects were unaware of this arrangement and no attention was drawn to the importance or significance of the elements.

In order to evaluate the recall and comprehension of subjects, a previously validated measurement tool comprised of a series of open-ended questions that focused on the eighteen elements of informed consent found in the American Association of Orthodontists (AAO)/MIC documents was used.^{31, 32} The open-ended nature of the questions sought to assess recall and comprehension rather than memorization of informed consent.³³ Within the interview sequence there were four rephrased recall questions aimed at testing internal reliability of subjects. Scenario-based questions

measured subject comprehension by presenting a situation and asking the subject how he/she would manage that particular situation.

Research assistants were trained in research protocol, subject recruitment, the consent process, and the interview procedure. Interviewing was conducted using a script that incorporated the measurement tool. Interviewers repeated and rephrased questions as necessary and encouraged subjects to answer all questions without leading their responses.

For all subjects, the orthodontist reviewed the reasons for the recommended treatment and the orthodontic treatment plan during the scheduled consultation appointment. For Group A, the orthodontist verbally reviewed the risks and limitations of treatment found on the MIC document with the patient and parent. For Group B, the MIC was not verbally reviewed by the orthodontist. In both groups the patient and parents were encouraged to read the MIC form for 10 to 15 minutes on their own and were given the opportunity to ask the orthodontist questions. Independently, patients and parents in both groups then viewed the customized computer-based slideshow presentation and were interviewed by the research assistants. Interviews were recorded. The intervention for Group C, from the study by Kang et al¹, was equivalent to Group A except all patient/parent pairs viewed an identical PPT (which also included the 18 consent elements).

The reading test portion of the Wide Range Achievement Test 3 (WRAT 3) (Wide Range in cooperation with PAR, Lutz, FL)³⁴ and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Terry Davis, Louisiana State University Medical

Center, Shreveport, LA)³⁵ were used to gauge overall reading ability and the health literacy reading ability of both patient and parent subjects. A self-administered questionnaire gathered socio-demographic information, a self-assessment of understanding of the risks, benefits, and limitations of orthodontic treatment on a visual analog scale (VAS), and state anxiety level using a six-item Spielberger State-Trait Anxiety Inventory (STAI-6).³⁶ Children who participated in the study were given a \$15 gift card.

Digital recordings of the interviews were transcribed verbatim. A previously developed codebook identified key words or phrases signifying recall and comprehension of the eighteen elements of informed consent.¹ The response rater reviewed and gained proficiency using the codebook with its authors prior to scoring the interviews for this study. Using the codebook, transcribed interviews were reviewed and the responses were scored as either 1) inappropriate 2) on-target (correct) 3) "I don't know/cannot remember" or 4) question skipped/no response given. As more interviews were scored, additional acceptable responses were identified and added to the codebook; these responses were re-coded for previous cases.

Four elements within the recall portion of the measurement tool were rephrased to test reliability of the patient and parent subjects. The response rater's inter-rater reliability was evaluated by scoring ten patient and ten parent interviews chosen at random from the previous data set from Kang et al¹ and compared to the scores of that study's response rater. Two weeks after their original scoring, the response rater rescored

ten patient and ten parent interviews from this study's data set to evaluate intra-rater reliability.

Statistical analysis

Simple Kappa statistics with 95% confidence intervals were calculated for the inter-rater (Kang et al¹ vs. present study) and intra-rater reliability as well as subject reliability. Data from the present study was combined with that from the Kang et al¹ for the remaining analysis. Descriptive statistics were calculated for socio-demographic data, REALM scores, WRAT 3 scores, STAI-6 scores, and VAS self-assessment scores. Among group differences for these potentially confounding variables were evaluated using analysis of variance (ANOVA) for age; Kruskal-Wallis test for REALM, WRAT3, STAI-6 and self-assessment scores; Chi-square test for gender; and Fisher exact tests for ethnic group and grade. Spearman correlation coefficients with Bonferroni corrections were used to calculate the correlations between mean percentage of on-target responses, REALM scores, WRAT 3 scores, STAI-6 scores, and VAS self-assessment scores. An ANOVA and Tukey-Kramer procedure were used to evaluate the following differences between Groups A, B, and Group C (the Kang et al¹ study): mean percentage of on-target responses for overall recall questions and comprehension questions; the domains of treatment, risk, and responsibility; and the core, custom, and general elements of the slideshow. The level of significant difference was set at $\alpha = 0.05$.

To further investigate the effect of ordering and determine whether the serial positioning effect³⁷⁻⁴⁰ was present for Groups A, B, and C, a second order polynomial

regression was applied to the percentage correct responses that were aligned with the order of the elements in the slideshow presentation. Previous authors Murdock⁴¹ and Bonk⁴² analyzed their serial positioning data using curvilinear functions.

RESULTS

Reproducibility for the scoring of the interview data was evaluated as inter-rater reliability (current rater versus previous rater) and was “excellent”⁴³ ($\kappa = 0.85$ (95% CI: 0.77, 0.94)). Intra-rater reliability for the interviews also was “excellent” ($\kappa = 0.86$ (95% CI: 0.79, 0.92)).

Internal reliability (Table 1) for all subjects in Groups A and B was “fair to substantial”⁴³ for three of the four questions with kappa scores ranging from 0.22 to 0.67. The questions regarding ankylosis had “slight” reliability with kappa scores of 0.18 (children) and 0.19 (adults).

Combining the present study data with that from the Kang et al¹ study for analysis seemed appropriate since both studies were conducted at the same institution and sampled similar populations within three years of each other (a period when no changes in patient management and treatment procedures were instituted). Results demonstrated excellent inter-rater reliability and no significant differences among the combined treatment groups for gender, age, ethnicity, education/grade level, parental income, REALM, WRAT 3, or STAI-6 (Table 2).

Within study differences: Correlations were calculated between correct response for question type (recall and comprehension for both patients and parents in Groups A

and B) and REALM, WRAT 3, STAI-6, and self-assessment of understanding. Only REALM was positively correlated with the percentage of correct recall responses for patients in Group A ($r = 0.60$, $p = 0.005$). Self-assessment of understanding was not significantly correlated with correct responses for any of the groups. Correlations were calculated among REALM, WRAT 3, STAI-6, and self-assessment of understanding by patients and parents. REALM and WRAT 3 scores were positively correlated for both patients and parents ($r = 0.72$ and 0.56 respectively, $p = 0.005$).

ANOVA tests compared groups on correct responses for overall recall and comprehension (Table 3) as well as the domains of treatment, risks, and responsibilities for recall and comprehension (Table 4). ANOVA tests were also used to compare question type by customization (general, core, or custom; see Table 5). The only significant difference between Groups A and B was found in the risk domain for the recall questions for patients; subjects in Group A had higher scores than Group B. There were no significant differences between Groups A and B for any question type or domain for parents.

Between study differences: Patients in Group A scored significantly higher than Group C for overall comprehension and for the risk domain for both recall and comprehension. Patients in Group A also scored significantly higher than Group C for general recall type questions. Patients in Group B scored significantly higher than Group C for overall comprehension, the treatment domain for recall, and the risk domain for comprehension. There were no significant differences between any of the groups for any question type or domain for parents.

A bow shaped regression line was apparent for both parents and patients in Groups A, B, and C for recall and comprehension when percentage of on-target responses was compared to the order in which question domains and types were presented in the slideshow (Figures 3-6). This regression line was significant for Groups A and B (child comprehension: $r = 0.60$, $p = 0.03$ and parent comprehension: $r = 0.62$, $p = 0.02$) and Group C (child recall: $r = 0.80$, $p = <0.0001$; parent recall: $r = 0.55$, $p = 0.01$; child comprehension: $r = 0.87$, $p < 0.0001$; and parent comprehension: $r = 0.89$, $p < 0.0001$). Although the regression line was also apparent for child and parent recall for Groups A and B, it did not reach the $p=.05$ level of significance.

DISCUSSION

True informed consent relies on the practitioner's ability to effectively communicate treatment goals as well as the benefits, risks, and limitations of treatment. It is also interactive; patients and their parents should feel comfortable seeking clarification to better understand the proposed treatment. This allows parents to truly make a participatory and informed decision about their child's care.

This informed consent study divided interview questions into two categories. One category was for the type of question: a recall type question (e.g. What are the risks to the tooth roots with braces on?) or a comprehension type question (e.g. Amy got her braces a few days ago. Her mouth is sore especially when she is eating. What would you do?). The other category was for the domains of: 1) treatment issues (e.g. extracting teeth due to extreme crowding), 2) risks (e.g. decalcifications and gingivitis) or 3) responsibilities

(e.g. brushing and flossing teeth). Our results show that while parents had greater recall and comprehension when compared with children, the percentage of on-target responses for recall (58% children, 71% parents) and comprehension (53% children, 68% parents) in this investigation were generally low and similar to the results of previous studies examining orthodontic informed consent.^{1, 11, 12} Although not significant, there was a 5% improvement for overall recall for children compared with a previous investigation using the same instrument.¹ There was also a significant 8% improvement for patients' overall comprehension in the current study compared with the previous study. Parent performance did not change from the previous study.

The current study's findings validate the method that combined written and audiovisual presentation of consent materials to improve readability and processability, respectively. In each case (Kang et al¹ and the current study) this method has substantially outperformed reported levels of the traditional and most commonly used AAO form.¹

On-target responses for comprehension were lower than recall scores in all areas except the domain for responsibility. These results are consistent with those from previous studies suggesting that when subjects are presented with an open-ended question format, they can correctly "parrot" responses for direct recall questions more easily than solve the scenario-based comprehension questions.^{1, 11, 12}

Within the domains of informed consent, on-target responses were generally highest for the responsibility domain for both parents and children. The one exception to this was Group A children who scored highest in the risk recall domain. Mortensen et al

examined patients' and parents' ability to recall specific treatments, risks, and responsibilities and compared the number recalled to those listed by the practitioner.¹² Our results showed more than double the risk recall scores for parents and more than three times the risk recall scores for children when compared with the results reported by Mortensen et al,¹² paralleling closely the findings from the study by Kang et al.^{1, 12} Our interview questions might have cued participants to appropriate responses whereas Mortensen et al's participants were asked to list the risks in an open-ended manner without context clues within the questions.

Treatment recall was higher for children in the Mortensen et al study (63%) as compared to our study's groups (48%) and the slideshow group in Kang et al's study¹ (37%), but similar for parents in all three of their study groups. Our interview assessed more complex aspects of treatment such as interproximal reduction and TMD. These treatment concepts might have been more challenging for child participants than Mortensen's questions about retainers or extractions. Responsibility recall was similar for children in all three studies. Responsibility recall was lower for parents in the Mortensen study (61%) than in our study (83%) and Kang et al's study (81%). Again on-target responses were generally highest for the responsibility domain for both parents and children and may be easier concepts to master.

The current study examined the effect of the practitioner's verbal explanation on recall and comprehension of eighteen informed consent elements. For the most part, patients and parents performed similarly with and without the additional verbal explanation for overall recall and comprehension as well as within the treatment domains.

For child subjects, the only area where the orthodontist's verbal explanation may be helpful is within the domain of risk, where children in Group A scored significantly higher than those in Group B for recall in this domain. This suggests that when utilizing our informed consent methodology (patient/parent review of the MIC form and viewing the "chunked" PPT presentation), the orthodontist's verbal explanation of risks and limitations of treatment did not add to parental understanding of the key elements of informed consent. These findings parallel previous research that showed that adult patients' understanding is similar when a concise versus traditional informed consent format is utilized.¹⁶ One possible explanation for subjects scoring similarly for the majority of question types is that the subjects are overwhelmed by the amount of information presented as well as the time it takes to convey it. Therefore, a shorter method may be equally informative because subjects are not as fatigued by the process.^{14,}
¹⁵ While it is likely that orthodontists explaining the planned orthodontic treatment would verbally highlight those elements of particular importance to that specific patient, it provided no benefit in this study. Undue repetition does not appear to be warranted.

Another goal of this study was to determine if the "chunked" informed consent PPT would improve the recall and comprehension of informed consent. There were some significant differences observed between patients in our study Groups A and B and the patient group with the standard PPT from the Kang et al¹ study, Group C. Although overall recall and comprehension in Group A and Group B were 5-9% greater than Group C, the real changes occurred in the risk domain. More specifically, risk recall improved by as much as 17% for Group A, and risk comprehension for Group A and Group B was

greater than 10% higher than for Group C. One explanation for the differences seen between Group C and the other groups is the order in which the informed consent elements were presented in the PPT. Treatment Groups A and B had predominantly more risk domain elements at the beginning of the PPT in the general risks and limitations “chunk” as compared to Group C. Better performance on these elements at the beginning of the slideshow, i.e. the primacy effect (Figures 3, 4, 5, and 6), is consistent with research that has demonstrated a bow shaped curve for memory recall such that items at the beginning are remembered better than those in the middle of a presentation.^{37-40, 42} This held true for all groups in this study. Because the elements were not identically presented in all groups, this speaks to the power of the primacy effect. As mentioned previously, our research indicates that, for children, the risk domain uniquely requires some verbal explanation. This explains why Group B did not have the same increase in recall.

Child treatment recall was significantly higher for Group B as compared to Group C. Group A recall did not differ significantly from Group C (47% vs. 37%) but was nearly indistinguishable from Group B (49%), suggesting that once again order of presentation plays a role in participant recall of the informed consent elements.

Treatment Groups A and B had more treatment domain elements as part of the general risks and limitations “chunk” in the PPT as compared with Group C. This is consistent with the primacy effect.^{37-40, 42}

Recall in the domain of responsibility showed no differences among the three groups for either children or their parents. The ordering of the elements in the slideshow

was similar between the two studies in the domain of responsibility. Because the end of each PPT was customized with different elements for each subject, statistical analysis for the latency effect (better performance on those elements at the end of the slideshow) was not completed. However, a higher percentage of on-target responses can be observed in Groups A and B (Figures 3 and 4).

It is possible that items addressed at the beginning of the PPT scored better for recall and comprehension than those toward the middle or end because research in learning has shown that when individuals learn, their short-term memories are limited to around seven new concepts at a time.⁴⁴ The informed consent elements that scored better in our study fall within the first items introduced to the subject. Moreover, once the limit of seven concepts is reached, the presentation of additional concepts leads to fewer overall items remembered.¹⁴ Presenting eighteen new orthodontic elements to patients and parents in one setting is an important limiting factor to consider when assessing understanding. This order effect was significant for child and parent comprehension in our study. If this is indeed true, then to have the most critical impact based on the psychological learning concepts and our data, one should address first the four core elements of informed consent and the issues that apply to the specific patient. It is plausible that the most important information should be presented first as we suggest or information beyond the first seven points should be provided as supplemental written material for perusal by patients and parents at another time or addressed at another time during treatment. The premise is that it is better to know the important issues than nothing at all. If one chooses to ignore the issue of the number of informed consent items

presented, then those deemed most important should be at the beginning and the end of the presentation-- understanding that the volume will negatively impact any learning that occurs at all points in the process.

In the current protocol, the order of the elements was rearranged without cuing the subjects to those elements that are most applicable to all patients or the patient-specific risk factors. Research that highlights these elements in the slideshow may lead to greater recall and comprehension.

Although the consenting parents' performance on recall and comprehension were not improved by the methods of this study, improvement in recall and comprehension by the child patient was demonstrated between groups in this study and compared to Kang et al.¹ These improvements in understanding can be critical due to the patients' intimate involvement with their treatment. Patient cooperation is essential to successful orthodontic outcomes.

The significant correlation between on-target recall responses and REALM for child subjects in Group A ($r = 0.60$) reinforces the link between a health literacy measure and knowledge recall. This finding is encouraging and not unexpected, but may be due to the large sample size and has limited ability to explain the variability observed. REALM and WRAT 3 scores were significantly and positively correlated for both parent and child participants. These variables explain less than half the variability and most likely reflect the overlap of reading ability and health literacy. This is congruent with the findings from Kang et al¹ and other studies.^{8, 11, 12, 45}

Each parent and patient participant evaluated their own understanding of the risks, benefits, and limitations of orthodontic treatment on a 0-10 cm visual analog scale. Median scores for self-assessment of understanding were very high for both parents (9.3cm) and patients (8.7cm). There was no significant correlation between subjects' perceived understanding and their actual percentage correct responses for recall and understanding. These findings were similar to previous studies emphasizing that those consenting have no knowledge of their true state of understanding.^{1, 46}

In this study, internal reliability of the subjects for the interview questions ranged from slight to substantial. The ankylosis questions may have covered a more challenging concept and therefore resulted in subject confusion and lower reliability. These reliability scores are comparable to those found in the study by Kang et al.¹ Intra- and inter-rater reliabilities were high, demonstrating the ability to successfully train other researchers and to sustain this measurement. It may be a useful tool for further informed consent research.

It appears, then, that in the short term (i.e. within one hour of the informed consent presentation with clinic-based patients), by using a modified informed consent document formatted for readability and a supplemental media presentation with priority ordered issues front loaded and limited in number, it is possible to reduce repetition and shorten the presentation without jeopardizing patient and parent recall and understanding; one may even improve it significantly in some critical areas. It may be advisable to eliminate or defer multiple or repeated presentations of less critical informed consent issues. Whether these techniques influence recall and comprehension of informed

consent and translate into observed behavior changes during treatment has not yet been documented.

CONCLUSIONS

1. There was little benefit to a verbal review of informed consent by the orthodontist when using the method described in this study (review of a readable format supported by a PPT presentation), with the exception of a presentation of the risks of treatment for child patients.
2. This method benefited assenting patients in the domains of treatment and risk recall more than their consenting parents.
3. Recall of informed consent was greater than comprehension for both patients and parents. Patients and parents continued to have reduced understanding of the risks and limitations of orthodontic treatment and did not realize this deficit.
4. Patients and parents understood best those informed consent elements presented first in the PPT. They should be presented the most important information first or given information beyond the first seven points as supplemental written material for their perusal at another time.
5. If one elects to address more than seven informed consent elements at once, then those deemed most important should be presented at the beginning and the end-- understanding that the volume will negatively impact the learning occurring at all points of the presentation.

References

1. Kang EY, Fields HW, Kiyak A, Beck FM, Firestone AR. Informed consent recall and comprehension in orthodontics: Traditional vs improved readability and processability methods. *Am J Orthod Dentofacial Orthop*. 2009;136:488.e1,13; discussion 488-9.
2. Kutner M, Greenberg E, Jin Y, Paulsen C. The health literacy of America's adults: Results from the 2003 national assessment of adult literacy (NCES 2006-483). Washington, DC: U.S. Department of Education: National Center for Education; 2006.
3. Easton P, Entwistle VA, Williams B. Health in the 'hidden population' of people with low literacy. A systematic review of the literature. *BMC Public Health*. 2010;10:459.
4. Miller E, Lee JY, DeWalt DA, Vann WF, Jr. Impact of caregiver literacy on children's oral health outcomes. *Pediatrics*. 2010;126:107-14.
5. DeWalt DA, Hink A. Health literacy and child health outcomes: A systematic review of the literature. *Pediatrics*. 2009;124 Suppl 3:S265-74.
6. Alexander RE. Readability of published dental educational materials. *J Am Dent Assoc*. 2000;131:937-42.
7. Harwood A, Harrison JE. How readable are orthodontic patient information leaflets? *J Orthod*. 2004;31:210,9; discussion 201.
8. Tait AR, Voepel-Lewis T, Malviya S, Philipson SJ. Improving the readability and processability of a pediatric informed consent document: Effects on parents' understanding. *Arch Pediatr Adolesc Med*. 2005;159:347-52.
9. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: A comparison of print, video, and computer-based presentations. *Patient Educ Couns*. 2004;53:205-16.
10. Rossi M, McClellan R, Chou L, Davis K. Informed consent for ankle fracture surgery: Patient comprehension of verbal and videotaped information. *Foot Ankle Int*. 2004;25:756-62.
11. Baird JF, Kiyak HA. The uninformed orthodontic patient and parent: Treatment outcomes. *Am J Orthod Dentofacial Orthop*. 2003;124:212-5.
12. Mortensen MG, Kiyak HA, Omnell L. Patient and parent understanding of informed consent in orthodontics. *Am J Orthod Dentofacial Orthop*. 2003;124:541-50.

13. Ernst S, Elliot T, Patel A, et al. Consent to orthodontic treatment--is it working? *Br Dent J.* 2007;202:E25; discussion 616-7.
14. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills.* 2nd Edition ed. Philadelphia, PA: J.B. Lippencott Co.; 1996.
15. Doak LG, Doak CC. Patient comprehension profiles: Recent findings and strategies. *Patient Couns Health Educ.* 1980;2:101-6.
16. Stunkel L, Benson M, McLellan L, et al. Comprehension and informed consent: Assessing the effect of a short consent form. *IRB.* 2010;32:1-9.
17. Scheurer PA, Firestone AR, Burgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1996;18:349-57.
18. Erdinc AM, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod.* 2004;26:79-85.
19. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1989;96:47-53.
20. Taithongchai R, Sookkorn K, Killiany DM. Facial and dentoalveolar structure and the prediction of apical root shortening. *Am J Orthod Dentofacial Orthop.* 1996;110:296-302.
21. Weltman B, Vig KW, Fields HW, Shanker S, Kaizar EE. Root resorption associated with orthodontic tooth movement: A systematic review. *Am J Orthod Dentofacial Orthop.* 2010;137:462,76; discussion 12A.
22. Killiany DM. Root resorption caused by orthodontic treatment: An evidence-based review of literature. *Semin Orthod.* 1999;5:128-33.
23. Linge BO, Linge L. Apical root resorption in upper anterior teeth. *Eur J Orthod.* 1983;5:173-83.
24. Mitchell L. Decalcification during orthodontic treatment with fixed appliances--an overview. *Br J Orthod.* 1992;19:199-205.
25. Mizrahi E. Enamel demineralization following orthodontic treatment. *Am J Orthod.* 1982;82:62-7.
26. Lovrov S, Hertrich K, Hirschfelder U. Enamel demineralization during fixed orthodontic treatment - incidence and correlation to various oral-hygiene parameters. *J Orofac Orthop.* 2007;68:353-63.

27. Gorelick L, Geiger AM, Gwinnett AJ. Incidence of white spot formation after bonding and banding. *Am J Orthod.* 1982;81:93-8.
28. Little RM. Stability and relapse of mandibular anterior alignment: University of Washington studies. *Semin Orthod.* 1999;5:191-204.
29. Ormiston JP, Huang GJ, Little RM, Decker JD, Seuk GD. Retrospective analysis of long-term stable and unstable orthodontic treatment outcomes. *Am J Orthod Dentofacial Orthop.* 2005;128:568,74; quiz 669.
30. Bondemark L, Holm AK, Hansen K, et al. Long-term stability of orthodontic treatment and patient satisfaction. A systematic review. *Angle Orthod.* 2007;77:181-91.
31. Kang EY, Fulks D, Fields HW, Beck FM, Kiyak HA, Firestone AR, Pope A. Pilot study: Developing a tool to measure orthodontic informed consent. *J Dent Res.* 2007;86:1675.
32. Kang EY, Pope A, Fields HW, et al. Clinical pilot study: Validating an orthodontic informed consent measurement tool. *J Dent Res.* 2007;86:1674.
33. Hochhauser M. Informed consent and patient's rights documents: A right, a rite, or a rewrite? *Ethics Behav.* 1999;9:1-20.
34. Wide Range Achievement Test (WRAT 3). Wilmington, DE: Wide Range Inc.; 1993.
35. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Fam Med.* 1993;25:391-5.
36. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the spielberger state-trait anxiety inventory (STAI). *Br J Clin Psychol.* 1992;31 (Pt 3):301-6.
37. Atkinson RC, Shiffrin RM. The control of short-term memory. *Sci Am.* 1971;225:82-90.
38. Bhatarah P, Ward G, Tan L. Examining the relationship between free recall and immediate serial recall: The serial nature of recall and the effect of test expectancy. *Mem Cognit.* 2008;36:20-34.
39. Bousfield WA, Whitmarsh GA, Esterson J. Serial position effects and the marbe effect in the free recall of meaningful words. *J Gen Psychol.* 1958;59:255-62.
40. Gershberg FB, Shimamura AP. Serial position effects in implicit and explicit tests of memory. *J Exp Psychol Learn Mem Cogn.* 1994;20:1370-8.

41. Murdock BB, Jr. The distinctiveness of stimuli. *Psychol Rev.* 1960;67:16-31.
42. Bonk WJ, Healy AF. Learning and memory for sequences of pictures, words, and spatial locations: An exploration of serial position effects. *Am J Psychol.* 2010;123:137-68.
43. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977;33:159-74.
44. Miller GA. The magical number seven plus or minus two: Some limits on our capacity for processing information. *Psychol Rev.* 1956;63:81-97.
45. Kiyak HA. Patients' perception of recovery after third molar surgery. *J Oral Maxillofac Surg.* 1999;57:1295.
46. Tait AR, Voepel-Lewis T, Malviya S. Do they understand? (part I): Parental consent for children participating in clinical anesthesia and surgery research. *Anesthesiology.* 2003;98:603-8.

1. Cavities, decalcification, gum disease
2. Discomfort
3. Injury from braces or injury from headgear
4. Health updates
5. Tobacco product use
6. Treatment time
7. Retainers
8. Impacted teeth and unerupted teeth
9. Root resorption
10. Large fillings and injured teeth that might need root canal therapy
11. Accidental injury during adjustment appointments
12. Abnormal jaw growth
13. Extractions and orthognathic surgery for severe crowding and mismatched jaws
14. Temporomandibular joint disorder (TMD)
15. Tooth reshaping and interproximal reduction
16. Ceramic appliances and damage to enamel
17. Wisdom teeth
18. Allergies to orthodontic appliances

Figure 1. Eighteen elements of orthodontic informed consent.

SECTION OF ORTHODONTICS

Research ID: _____

YOUR CONSENT FOR ORTHODONTIC TREATMENT (BRACES)

Orthodontic treatment (braces) can help you have a pleasing smile. You should know that treatment with braces has limits and possible risks. All health treatments, including braces, have some limits and risks. Your treatment with braces usually goes as planned but results cannot be guaranteed. The good news is that the risks with braces are usually minor and do not happen very often, but you should know about them before choosing braces. The following are possible risks and how you can help reduce the risks.

RISKS

WHAT YOU CAN DO

Cavities, Decalcification, Gum disease You can get cavities (tooth decay), gum disease, or decalcification (permanent white or brown spots on your teeth) if you eat foods with a lot of sugar or do not clean your teeth often and properly. Your gums can bleed, get puffy, red, and infected (gingivitis). You can also lose the bone that holds your teeth (periodontal disease). The chance of having these problems is greater when you have braces.	<ul style="list-style-type: none">▪ Watch your diet - Avoid sugar and sticky foods.▪ Remove the plaque (build up of food and germs) from your teeth by brushing and flossing your teeth every day.▪ Get regular dental check ups with your dentist while you are in braces.
Discomfort Getting braces and having adjustments to straighten your teeth can make your teeth and mouth sensitive or sore. Everyone is different, but in general, the soreness usually lasts 24 to 48 hours.	<ul style="list-style-type: none">▪ You can take over-the-counter nonaspirin pain medicine to help relieve soreness if allowed by your doctor. Otherwise, use what your doctor recommends.▪ Tell us right away if anything seems unusual.
Damage to braces or teeth Parts of your braces may become loose or break if you get hit in the mouth or face from sports or horseplay. Eating hard foods can also break your braces. Mouth jewelry and piercings around the lips can damage your gums, lips and teeth.	<ul style="list-style-type: none">▪ Wear a mouthguard when you are playing any sport.▪ A mouthguard can protect your teeth and braces from breaking or getting loose.▪ Avoid hard foods.▪ Avoid piercing or keeping a piercing in your tongue, lip, or any part of your mouth.
Injury from braces Your braces may poke or scratch your mouth. Also, if parts of your braces become loose or break they may be swallowed or inhaled (breathed into the lungs). Injury from headgears Even though headgears have a safety system, they can be dangerous. They can hurt your eyes and face.	<ul style="list-style-type: none">▪ Tell us if your braces are hurting you or are loose or broken.▪ Do not wear your headgear outside of the house, during horseplay, or while playing sports.▪ Follow your orthodontist's directions.
Health updates Many medical problems can affect your progress with braces.	<ul style="list-style-type: none">▪ Tell us about your health and all medications.▪ Tell us when there are any changes to your health, including pregnancy and medications.
Using Tobacco Products Using tobacco (smoking or smokeless tobacco) can increase your chance of getting gum disease and slows down healing in your mouth. Tobacco can also increase your chance of getting sores in your mouth and hurt your health.	<ul style="list-style-type: none">▪ Avoid using tobacco products.▪ If you continue to use tobacco, you should know that you may get a less than ideal result with your braces.

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Figure 2. Modified informed consent (MIC) document (copyright 2008, The Ohio State University)

continued

Figure 2 continued

<u>RISKS</u>	<u>WHAT YOU CAN DO</u>
<p>Treatment time Your time in braces is only an estimate. The actual time in braces may be longer. The following can affect your time in braces and affect the end result: how you grow, how well you wear your rubber bands and other parts of your braces, and if you come to all of your scheduled appointments.</p>	<ul style="list-style-type: none"> ▪ Wear your rubber bands and other parts of your braces as instructed by your orthodontist. ▪ Come to all of your scheduled appointments. ▪ Come to your appointments on time.
<p>Retainers When you get your braces off, your teeth will want to move back toward their starting positions. Your teeth and bite are always changing throughout life. Teeth may change because you are still growing or you have oral habits. There may also be other unknown reasons.</p>	<ul style="list-style-type: none"> ▪ You should wear a retainer to help keep your teeth straight. ▪ Retainers should be worn for as long as you want to keep your teeth straight.

LIMITS
Our goal is to give you the best result possible. There are limits to what braces can do and some things are uncontrollable. The following are the possible limits of braces and other things you should know about braces.

- **Impacted teeth** (teeth that are stuck in the jaw) and **unerupted teeth** (teeth that have not come into the mouth) can be problems. They can cause loss of teeth, gum problems, and shortening of roots. Sometimes these teeth can be pulled into the mouth. Some teeth become ankylosed (tooth fused to the bone) and will not move. These teeth may have to be removed. These problems mean you may be in braces longer.
- Having braces can sometimes cause the roots of your teeth to get shorter. This is called **root resorption**. A past injury of your teeth can increase your chances of having this happen. In general, shortened roots are not a severe problem but can sometimes lead to early loss of the teeth that are affected. If you get root resorption, we may stop or slow down your treatment for a while.
- A large filling or an injury to a tooth from a past accident can **damage the nerve** inside the tooth. Straightening injured teeth can sometimes irritate the nerve and you may need to have a root canal on that tooth.
- Sometimes the dental instruments we use in your mouth can accidentally poke, scratch, or bump your mouth, gums, or teeth.
- **Abnormal jaw growth** can affect your end result and change your treatment. If your teeth and jaws do not grow as expected, your bite will change. If you have braces when this happens, you might need to be in braces longer or have jaw surgery. If abnormal tooth or jaw growth happens after you get your braces off, you may need to have braces again. Abnormal growth is something we cannot predict or control.
- You may need to have some **teeth removed or orthognathic surgery (jaw surgery)** as part of your treatment. This is usually needed to fix severe crowding or severe mismatch of the jaws.
- Problems can occur in the jaw joints making it hard to open your mouth, giving you joint pain, headaches, ear aches, or pain when chewing. These are sometimes called **Temporomandibular Joint Disorders (TMD or TMJ)**. If you have any of these problems, please tell us right away. We may send you to a specialist to have these problems treated. Braces do not cause or cure TMD or TMJ.
- **Braces alone may not provide the best result.** The best result may require changing the shape and size of your teeth. These may include reshaping or flattening some of your teeth by grinding the enamel or adding filling material to make your teeth a different size. Your dentist can help make these changes and answer your questions about these procedures.

2/3

continued

Figure 2 continued

- **Clear or tooth-colored braces** have been known to break and damage teeth. When the braces are taken off, they can crack or cause flaking of the teeth. There is a risk of swallowing or inhaling the bracket if it breaks.
- **Wisdom teeth** can sometimes cause problems with your teeth and jaws. We will let you know if they need to be removed. Your dentist may also discuss wisdom teeth with you. Please let us know what your dentist recommends before you have anything done.
- Some patients are **allergic to the materials in the braces and rubber bands**. The braces may need to be stopped. Sometimes, special braces can be used or we may have to do a different plan for your teeth. You may need to see a medical doctor to control the allergy.

POSSIBLE OPTIONS

Getting braces is a choice for you to make. There may be more than one good way to fix your teeth and mouth. Sometimes there is only one good choice. You do not have to change your mouth and teeth.

CONSENT TO HAVE ORTHODONTIC TREATMENT (BRACES)

I have read, understood and have had all of my questions answered about the risks and limits of braces. I have been told by my orthodontist about the problems they have found and how they can be fixed. My orthodontist has also told me about any problems that may come up during my treatment with braces. I understand that things can change while I am in braces and the risk of continuing with braces may become greater than the benefits. The braces should be stopped if this happens. I know that treatment generally goes as planned but my results are not guaranteed. I understand that extra dental procedures, like jaw or gum surgery, implants, root canals, reshaping teeth and/or fillings are a separate cost from the braces.

All of the information I need to make a decision has been given to me. I was able to ask all of my questions about my treatment and this form. I consent (give my permission) to having treatment.

USE OF RECORDS AGREEMENT

The Ohio State University Orthodontic Clinic is a patient treatment and learning center. I know that during my appointments, there may be other people observing for learning purposes. My records (pictures of my face and teeth, x-rays, or models of myself) may be used for consultations, teaching, publication in dental books and journals, or for display at scientific meetings. My name will not be included with the records. I consent to the use of my records by The Ohio State University Section of Orthodontics for these purposes.

KEEPING MY BRACES AND TEETH CLEAN (ORAL HYGIENE AGREEMENT)

I know that it is my responsibility to keep my braces and teeth clean. I must see my family dentist at least every 6 months. If I do **NOT** keep my braces and teeth clean while I have my braces, I know that any or all of the following bad things may occur: permanent discoloration of my teeth, cavities, or gum disease. If any of the above things occur because my braces and teeth are not clean, I know that I may need treatment by my family dentist or a dental specialist.

KEEPING MY APPOINTMENTS

If I cannot keep my appointment, 24 hours notice is required and I must cancel my appointment by calling (614) 292-9100. This helps the staff schedule another patient to take my place. If I cancel an appointment less than 24 hours in advance or do not show for an appointment, it will be considered a **no-show**. A **no-show** hurts 4 people: a patient that could have used my time, my orthodontist, the faculty supervising my care, and myself. After 3 **no-shows**, I will be considered uncooperative. I may not be able to continue being a patient in this clinic. My care in this clinic will be reconsidered.

URGENT PROBLEMS

If I have an urgent problem with my braces between 4:30 pm and 7:30 am, Monday to Friday or anytime on weekends, I can page my orthodontist. If s/he is unavailable, I can call (614) 293-8000 and ask for the GPR Resident on call.

Patient, Parent or Legal Guardian Signature _____ Date: _____ Resident _____ Date: _____

Figure 3. Percentage on-target recall responses for Groups A and B by element as presented in the slideshow.

The 2nd order polynomial regression displays a bow consistent with the serial order effect for patients and parents. Child regression: $y = 0.3991x^2 - 7.7696x + 85.168$, $r = 0.37$, $p = 0.11$; Parent regression: $y = 0.3186x^2 - 6.356x + 93.917$; $r = 0.37$, $p = 0.12$. Note that some elements had multiple questions.

Figure 4. Percentage on-target comprehension responses for Groups A and B by element as presented in the slideshow.

The 2nd order polynomial regression displays a bow consistent with the serial order effect for patients and parents. Child regression: $y = 1.237x^2 - 16.696x + 86.016$, $r = 0.60$, $p = 0.03$; Parent regression: $y = 0.9688x^2 - 12.88x + 92.169$, $r = 0.62$, $p = 0.02$. Note that some elements had multiple questions.

Figure 5. Percentage on-target recall responses for Group C by element as presented in the slideshow.

The 2nd order polynomial regression displays the serial order effect for patients and parents. Child regression equation: $y = 0.4046x^2 - 11.223x + 96.445$, $r = 0.80$, $p < 0.0001$; Parent regression equation: $y = 0.4713x^2 - 10.12x + 109.01$, $r = 0.55$, $p = 0.01$. Note that some elements had multiple questions.

Figure 6. Percentage on-target comprehension responses for Group C by element as presented in the slideshow.

The 2nd order polynomial regression displays the serial order effect for patients and parents. Child regression equation: $y = 0.3083x^2 - 9.1885x + 75.971$, $r = 0.87$, $p < 0.0001$; Parent regression equation: $y = 0.3159x^2 - 9.5948x + 95.114$, $r = 0.89$, $p < 0.0001$. Note that some elements had multiple questions.

Table 1. Internal reliability for patients and parents

<i>Question</i>	<i>Parent kappa (CI)*</i>	<i>Reliability</i>	<i>Patient kappa (CI)*</i>	<i>Reliability⁴³</i>
Retainers	0.41 (0.09-0.72)	Moderate	0.51 (0.23-0.79)	Moderate
Health updates	0.56 (0.11-1.00)	Moderate	0.22 (-0.02-0.45)	Fair
TMJ/TMD	0.67 (0.50-0.83)	Substantial	0.51 (0.27-0.75)	Moderate
Ankylosis	0.19 (0.04-0.34)	Slight	0.18 (0.01-0.34)	Slight

TMJ/TMD, Temporomandibular joint/temporomandibular disorder.

* Lower 95% to upper 95% confidence bounds.

⁴³ Landis and Koch.

Table 2. Sociodemographic data and REALM, WRAT 3, STAI-6, and self-assessment for patients and parents

<i>Subject</i>	<i>Group</i>	<i>Sex</i>	<i>Age (y)</i> (mean [$\pm$ SD])	<i>Educational</i> <i>level (median)</i>	<i>Ethnicity*</i> (%)	<i>Income</i> (median)	<i>REALM</i> (median)	<i>WRAT 3</i> (median)	<i>STAI-6</i> (median)	<i>Self-</i> <i>assessment/</i> <i>understanding</i> (mean [$\pm$ SD]) VAS
Patient	A	67.5% F n=40 32.5% M	14.4 (1.5)	8 th grade	66.7 WNH 15.4 BNH 12.8 WH 2.6 EA 2.6 mixed		7 th -8 th grade	High school	9.0	8.10 (1.76)
	B	55% F n=40 45% M	14.3 (1.6)	8 th grade	72.5 WNH 17.5 BNH 7.5 mixed 2.5 WH		High school	High school	9.5	8.30 (1.69)
	C	43%F n=30 57%M	14.6 (1.7)	8 th grade	73.3 WNH 20.0 BNH 3.3 WH 3.3 mixed		High school	High school	10.0	7.46 (1.7)
<i>P</i> value		0.13	0.80	0.68	0.62		0.19	0.69	0.97	0.07
Parent	A	80% F n=40 20% M	41.9 (9.0)	<4 years college	74.4 WNH 15.4 BNH 2.6 WH 2.6 EA 2.6 NA 2.6 mixed	\$25,000- \$49,999	High school	High school	9.5	8.77 (1.25)
	B	80% F n=40 20% M	43.8 (8.2)	<4 years college	75.0 WNH 17.5 BNH 5.0 WH 2.5 mixed	\$50,000- \$74,999	High school	High school	9.0	9.17 (0.94)
	C	80.0%F n=30 80.0%M	42.0 (6.6)	<4 years college	73.3 WNH 20.0 BNH 3.3 WH 3.3 mixed	\$25,000- \$49,999	High school	High school	7.0	9.02 (1.09)
<i>P</i> value		1.00	0.50	0.93	1.00	0.13	0.09	0.59	0.18	0.43

F, Female; M, male.

* WNH, White non-Hispanic; WH, White Hispanic; BNH, Black non-Hispanic; BH, Black Hispanic; EA, East Asian or Pacific Islander.

Group A = with verbal explanation; Group B = without verbal explanation; Group C = Kang et al¹ data for Modified informed consent document supplemented by a slideshow presentation.

Table 3. Mean (SD) percentages of on-target recall and comprehension for all patient and parent treatment groups

<i>Subject</i>	<i>Group</i>	<i>Recall</i>	<i>Recall comparisons^a</i>	<i>Comprehension</i>	<i>Comprehension comparisons^a</i>
Patient	A	58.8 (14.8)	X	52.9 (15.8)	X*
	B	57.4 (13.4)	X	53.6 (13.3)	X*
	C	52.6 (14.4)	X	44.2 (16.7)	Y
Parent	A	71.0 (13.9)	X	67.1 (13.3)	X
	B	70.6 (13.9)	X	69.2 (15.2)	X
	C	67.3 (16.8)	X	66.3(16.6)	X

* $P \leq 0.05$.

^a Similar letters indicate no statistically significant differences among the informed consent forms for either patients or parents by ANOVA.

Group A = with verbal explanation; Group B = without verbal explanation; Group C = Kang et al¹ data for Modified informed consent document supplemented by a slideshow presentation.

Table 4. Mean (SD) percentages of on-target responses for consent domains for patient and parent treatment groups

<i>Subject</i>	<i>Group</i>	<i>Domain</i>	<i>Recall</i>	<i>Recall comparisons^a</i>	<i>Comprehension</i>	<i>Comprehension comparisons^a</i>
Patient	A	TX	47.0 (19.3)	X,Y	40.9 (24.5)	X
	B	TX	48.9 (19.0)	X*	39.0 (20.0)	X
	C	TX	36.7 (22.9)	Y	32.7 (23.8)	X
	A	RK	68.6 (20.6)	X	41.6 (17.4)	X [†]
	B	RK	57.4 (18.5)	Y*	38.9 (18.5)	X*
	C	RK	51.3 (20.3)	Y [‡]	28.1 (19.7)	Y
	A	RS	67.4 (18.5)	X	72.3 (17.8)	X
	B	RS	68.6 (18.5)	X	78.2 (15.5)	X
	C	RS	70.7 (18.3)	X	68.2 (23.0)	X
Parent	A	TX	60.8 (21.5)	X	52.4 (22.8)	X
	B	TX	62.1 (27.0)	X	59.6 (26.4)	X
	C	TX	62.3 (24.5)	X	56.4 (24.1)	X
	A	RK	72.4 (17.4)	X	58.2 (19.9)	X
	B	RK	69.6 (19.3)	X	57.5 (20.5)	X
	C	RK	66.0 (22.0)	X	52.2 (21.1)	X
	A	RS	84.2 (15.7)	X	85.6 (15.6)	X
	B	RS	80.8 (15.9)	X	86.8 (13.1)	X
	C	RS	80.5 (17.8)	X	87.0 (18.3)	X

TX, Treatment; RK, risk; RS, treatment responsibilities.

* $P \leq 0.05$; [†] $P \leq 0.01$; [‡] $P \leq 0.001$.

^a Similar letters indicate no statistically significant differences among the informed consent forms for either patients or parents by ANOVA.

Group A = with verbal explanation; Group B = without verbal explanation; Group C = Kang et al¹ data for Modified informed consent document supplemented by a slideshow presentation.

TX= treatment related issues; RK= risk related issues; RS= responsibility related issues

Table 5. Mean (SD) percentages of on-target responses for general, core and custom type questions for all patient and parent treatment groups

<i>Subject</i>	<i>Group</i>	<i>Question type</i>	<i>Recall</i>	<i>Recall comparisons^a</i>	<i>Comprehension</i>	<i>Comprehension comparisons^a</i>
Patient	A	GEN	58.0 (15.5)	X [†]	39.8 (18.4)	X
	B	GEN	51.8 (15.3)	X,Y	39.7 (19.0)	X
	C	GEN	47.2 (14.5)	Y	32.5 (15.4)	X
	A	COR	58.9 (20.8)	X	68.5 (18.7)	X
	B	COR	65.7 (17.9)	X	70.6 (15.6)	X
	C	COR	62.5 (20.9)	X	60.7 (22.7)	X
	A	CUS	55.0 (35.9)	X	45.7 (38.6)	X
	B	CUS	55.7 (33.3)	X	46.3 (36.7)	X
	C	CUS	n/a	X	n/a	X
Parent	A	GEN	70.2 (14.7)	X	56.9 (17.6)	X
	B	GEN	67.3 (16.1)	X	57.5 (19.6)	X
	C	GEN	65.9 (18.3)	X	55.9 (19.4)	X
	A	COR	71.1 (19.2)	X	81.2 (16.6)	X
	B	COR	75.5 (15.6)	X	83.8 (13.3)	X
	C	COR	68.9 (19.1)	X	80.9 (18.1)	X
	A	CUS	68.7 (37.1)	X	56.0 (35.6)	X
	B	CUS	70.9 (31.1)	X	62.7 (39.0)	X
	C	CUS	n/a	X	n/a	X

[†] $P \leq 0.01$

^a Similar letters indicate no statistically significant differences among the informed consent forms for either patients or parents by ANOVA.

Group A = with verbal explanation; Group B = without verbal explanation; Group C = Kang et al¹ data for Modified informed consent document supplemented by a slideshow presentation.

GEN = general questions; COR = core questions; CUS = custom questions.

CHAPTER 4

CONCLUSIONS

1. There was little benefit to a verbal review of informed consent by the orthodontist when using the method described in this study (review of a readable format supported by a PPT presentation), with the exception of a presentation of the risks of treatment for child patients.
2. This method benefited assenting patients in the domains of treatment and risk recall more than their consenting parents.
3. Recall of informed consent was greater than comprehension for both patients and parents. Patients and parents continued to have reduced understanding of the risks and limitations of orthodontic treatment and did not realize this deficit.
4. Patients and parents understood best those informed consent elements presented first in the PPT. They should be presented the most important information first or given information beyond the first seven points as supplemental written material for their perusal at another time.
5. If one elects to address more than seven informed consent elements at once, then those deemed most important should be presented at the beginning and the end-- understanding that the volume will negatively impact the learning occurring at all points of the presentation.

BIBLIOGRAPHY

1. Health literacy: Report of the council on scientific affairs. ad hoc committee on health literacy for the council on scientific affairs, American Medical Association. JAMA. 1999;281:552-7.
2. Alexander RE. Readability of published dental educational materials. J Am Dent Assoc. 2000;131:937-42.
3. Atkinson RC, Shiffrin RM. The control of short-term memory. Sci Am. 1971;225:82-90.
4. Baird JF, Kiyak HA. The uninformed orthodontic patient and parent: Treatment outcomes. Am J Orthod Dentofacial Orthop. 2003;124:212-5.
5. Beckwith FR, Ackerman RJ,Jr, Cobb CM, Tira DE. An evaluation of factors affecting duration of orthodontic treatment. Am J Orthod Dentofacial Orthop. 1999;115:439-47.
6. Bhatarah P, Ward G, Tan L. Examining the relationship between free recall and immediate serial recall: The serial nature of recall and the effect of test expectancy. Mem Cognit. 2008;36:20-34.
7. Bondemark L, Holm AK, Hansen K, et al. Long-term stability of orthodontic treatment and patient satisfaction. A systematic review. Angle Orthod. 2007;77:181-91.
8. Bonk WJ, Healy AF. Learning and memory for sequences of pictures, words, and spatial locations: An exploration of serial position effects. Am J Psychol. 2010;123:137-68.
9. Bousfield WA, Whitmarsh GA, Esterson J. Serial position effects and the marble effect in the free recall of meaningful words. J Gen Psychol. 1958;59:255-62.
10. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: A comparison of print, video, and computer-based presentations. Patient Educ Couns. 2004;53:205-16.

11. Chung V, Horowitz AM, Canto MT, Siriphant P. Oral cancer educational materials for the general public: 1998. *J Public Health Dent.* 2000;60:49-52.
12. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: A shortened screening instrument. *Fam Med.* 1993;25:391-5.
13. DeWalt DA, Hink A. Health literacy and child health outcomes: A systematic review of the literature. *Pediatrics.* 2009;124 Suppl 3:S265-74.
14. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills.* 2nd Edition ed. Philadelphia, PA: J.B. Lippencott Co.; 1996.
15. Doak LG, Doak CC. Patient comprehension profiles: Recent findings and strategies. *Patient Couns Health Educ.* 1980;2:101-6.
16. Easton P, Entwistle VA, Williams B. Health in the 'hidden population' of people with low literacy. A systematic review of the literature. *BMC Public Health.* 2010;10:459.
17. Erdinc AM, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod.* 2004;26:79-85.
18. Ernst S, Elliot T, Patel A, et al. Consent to orthodontic treatment--is it working? *Br Dent J.* 2007;202:E25; discussion 616-7.
19. Gershberg FB, Shimamura AP. Serial position effects in implicit and explicit tests of memory. *J Exp Psychol Learn Mem Cogn.* 1994;20:1370-8.
20. Gorelick L, Geiger AM, Gwinnett AJ. Incidence of white spot formation after bonding and banding. *Am J Orthod.* 1982;81:93-8.
21. Harwood A, Harrison JE. How readable are orthodontic patient information leaflets? *J Orthod.* 2004;31:210,9; discussion 201.
22. Hochhauser M. Informed consent and patient's rights documents: A right, a rite, or a rewrite? *Ethics Behav.* 1999;9:1-20.
23. Jaknke JC. Serial position effects in immediate recall. *J Verb Learn Verb Beh.* 1963;2:284-7.
24. Jastak J, Wilkenson G. *Wide Range Achievement Test (WRAT-3).* Third Edition ed. Wilmington, DE: Wide Range, Inc.; 1993.
25. Jovic-Vranes A, Bjegovic-Mikanovic V, Marinkovic J, Kocev N. Health literacy in a population of primary health-care patients in Belgrade, Serbia. *Int J Public Health.* 2010.

26. Kang EY, Fulks D, Fields HW, Beck FM, Kiyak HA, Firestone AR, Pope A. Pilot study: Developing a tool to measure orthodontic informed consent. *J Dent Res*. 2007;86:1675.
27. Kang EY, Pope A, Fields HW, et al. Clinical pilot study: Validating an orthodontic informed consent measurement tool. *J Dent Res*. 2007;86:1674.
28. Kang EY, Fields HW, Kiyak A, Beck FM, Firestone AR. Informed consent recall and comprehension in orthodontics: Traditional vs improved readability and processability methods. *Am J Orthod Dentofacial Orthop*. 2009;136:488.e1,13; discussion 488-9.
29. Kilbridge KL, Fraser G, Krahn M, et al. Lack of comprehension of common prostate cancer terms in an underserved population. *J Clin Oncol*. 2009;27:2015-21.
30. Killiany DM. Root resorption caused by orthodontic treatment: An evidence-based review of literature. *Semin Orthod*. 1999;5:128-33.
31. Kiyak HA. Patients' perception of recovery after third molar surgery. *J Oral Maxillofac Surg*. 1999;57:1295.
32. Klein A. Informed consent: A practical approach. *Risk Manage Rep*. 1988;1:1-3.
33. Kutner M, Greenberg E, Baer J. A first look at the literacy of America's adults in the 21st century. Washington, D.C.: U.S. Department of Education. National Center for Education Statistics; 2006;NCES 2006-470.
34. Kutner M, Greenberg E, Jin Y, Paulsen C. The health literacy of America's adults: Results from the 2003 national assessment of adult literacy (NCES 2006-483). Washington, DC: U.S. Department of Education: National Center for Education; 2006.
35. Kutner M, Greenberg E, Jin Y, Boyle B, Hsu Y, Dunleavy E. Literacy in everyday life: Results from the 2003 national assessment of adult literacy. Washington, DC: U.S. Department of Education: National Center for Education Statistics; 2007;NCES 2007-480.
36. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-74.
37. Levander E, Malmgren O. Evaluation of the risk of root resorption during orthodontic treatment: A study of upper incisors. *Eur J Orthod*. 1988;10:30-8.
38. Ley P. Memory for medical information. *Br J Soc Clin Psychol*. 1979;18:245-55.

39. Linge BO, Linge L. Apical root resorption in upper anterior teeth. *Eur J Orthod.* 1983;5:173-83.
40. Little RM. Stability and relapse of mandibular anterior alignment: University of Washington studies. *Semin Orthod.* 1999;5:191-204.
41. Lovrov S, Hertrich K, Hirschfelder U. Enamel demineralization during fixed orthodontic treatment - incidence and correlation to various oral-hygiene parameters. *J Orofac Orthop.* 2007;68:353-63.
42. Lupi JE, Handelman CS, Sadowsky C. Prevalence and severity of apical root resorption and alveolar bone loss in orthodontically treated adults. *Am J Orthod Dentofacial Orthop.* 1996;109:28-37.
43. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the spielberger state-trait anxiety inventory (STAI). *Br J Clin Psychol.* 1992;31 (Pt 3):301-6.
44. Miller E, Lee JY, DeWalt DA, Vann WF, Jr. Impact of caregiver literacy on children's oral health outcomes. *Pediatrics.* 2010;126:107-14.
45. Miller GA. The magical number seven plus or minus two: Some limits on our capacity for processing information. *Psychol Rev.* 1956;63:81-97.
46. Mitchell L. Decalcification during orthodontic treatment with fixed appliances--an overview. *Br J Orthod.* 1992;19:199-205.
47. Mizrahi E. Enamel demineralization following orthodontic treatment. *Am J Orthod.* 1982;82:62-7.
48. Mortensen MG, Kiyak HA, Omnell L. Patient and parent understanding of informed consent in orthodontics. *Am J Orthod Dentofacial Orthop.* 2003;124:541-50.
49. Murdock BB, Jr. The distinctiveness of stimuli. *Psychol Rev.* 1960;67:16-31.
50. National Institute of Dental and Craniofacial Research, National Institute of Health, U.S. Public Health Service, Department of Health and Human Services. The invisible barrier: Literacy and its relationship with oral health. A report of a workgroup sponsored by the national institute of dental and craniofacial research, national institute of health, U.S. public health service, department of health and human services. *J Public Health Dent.* 2005;65:174-82.
51. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1989;96:47-53.

52. Ormiston JP, Huang GJ, Little RM, Decker JD, Seuk GD. Retrospective analysis of long-term stable and unstable orthodontic treatment outcomes. *Am J Orthod Dentofacial Orthop.* 2005;128:568,74; quiz 669.
53. Ozar D, Sokol D. *Dental Ethics at Chairside: Professional Principles and Practical Applications.* Washington D.C.: Georgetown University Press; 2002.
54. Powers BJ, Trinh JV, Bosworth HB. Can this patient read and understand written health information? *JAMA.* 2010;304:76-84.
55. Richman JA, Lee JY, Rozier RG, Gong DA, Pahel BT, Vann WF, Jr. Evaluation of a word recognition instrument to test health literacy in dentistry: The REALD-99. *J Public Health Dent.* 2007;67:99-104.
56. Rossi M, McClellan R, Chou L, Davis K. Informed consent for ankle fracture surgery: Patient comprehension of verbal and videotaped information. *Foot Ankle Int.* 2004;25:756-62.
57. Scheurer PA, Firestone AR, Burgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1996;18:349-57.
58. Stunkel L, Benson M, McLellan L, et al. Comprehension and informed consent: Assessing the effect of a short consent form. *IRB.* 2010;32:1-9.
59. Tait AR, Voepel-Lewis T, Malviya S. Do they understand? (part I): Parental consent for children participating in clinical anesthesia and surgery research. *Anesthesiology.* 2003;98:603-8.
60. Tait AR, Voepel-Lewis T, Malviya S, Philipson SJ. Improving the readability and processability of a pediatric informed consent document: Effects on parents' understanding. *Arch Pediatr Adolesc Med.* 2005;159:347-52.
61. Tait AR, Voepel-Lewis T, Zikmund-Fisher BJ, Fagerlin A. The effect of format on parents' understanding of the risks and benefits of clinical research: A comparison between text, tables, and graphics. *J Health Commun.* 2010;15:487-501.
62. Tait AR, Voepel-Lewis T, Zikmund-Fisher BJ, Fagerlin A. Presenting research risks and benefits to parents: Does format matter? *Anesth Analg.* 2010;111:718-23.
63. Taithongchai R, Sookkorn K, Killiany DM. Facial and dentoalveolar structure and the prediction of apical root shortening. *Am J Orthod Dentofacial Orthop.* 1996;110:296-302.
64. Thomson AM, Cunningham SJ, Hunt NP. A comparison of information retention at an initial orthodontic consultation. *Eur J Orthod.* 2001;23:169-78.

65. Wallace LS, Rogers ES, Roskos SE, Holiday DB, Weiss BD. Brief report: Screening items to identify patients with limited health literacy skills. *J Gen Intern Med*. 2006;21:874-7.
66. Weiner MF, Lovitt R. An examination of patients' understanding of information from health care providers. *Hosp Community Psychiatry*. 1984;35:619-20.
67. Weltman B, Vig KW, Fields HW, Shanker S, Kaizar EE. Root resorption associated with orthodontic tooth movement: A systematic review. *Am J Orthod Dentofacial Orthop*. 2010;137:462,76; discussion 12A.
68. Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of class II malocclusion. *Am J Orthod Dentofacial Orthop*. 2002;121:9-17.
69. Yin HS, Johnson M, Mendelsohn AL, Abrams MA, Sanders LM, Dreyer BP. The health literacy of parents in the united states: A nationally representative study. *Pediatrics*. 2009;124 Suppl 3:S289-98.

APPENDIX A: CONSENT

CONSENT
Biomedical/Cancer

IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0

The Ohio State University Consent to Participate in Research

Study Title: A New Approach to Orthodontic Informed Consent

Principal Investigator: Henry W. Fields, Jr.

Sponsor: Delta Dental Master's Thesis Grant

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

We would like to know how well we are communicating with our patients and their parents during our consultation appointment and improve this if needed.

2. How many people will take part in this study?

We hope to have 160 people in this study.

3. What will happen if I take part in this study?

You and your child will be randomly assigned (by chance) to one of two research study groups. You will have your normally scheduled consultation appointment with your orthodontic resident. The resident will review all the information about your child's orthodontic problem and how to best treat it. You and your child may review the informed consent document. You and your child will be asked to watch a short informational slide show, then to complete a questionnaire and then interviewed separately on what the resident discussed with you. Both of you will also

be asked to read a list of words that may or may not be familiar to you. You also will be asked how you feel.

4. How long will I be in the study?

The study will take approximately 45-60 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There are no anticipated risks, side effects or discomforts from being in the study.

7. What benefits can I expect from being in the study?

You will not expect to have any benefits from the study. This study may benefit others in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

10. What are the costs of taking part in this study?

Participating in this study may make your appointment longer than normal.

11. Will I be paid for taking part in this study?

Your child will be given a \$15 gift certificate.

By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Henry Fields or Dr. Kelly Carr.

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-1120

Kelly Carr
The Ohio State University College of Dentistry
Section of Orthodontics
305 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-9100

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Henry Fields or Dr. Kelly Carr.

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-1120

Kelly Carr
The Ohio State University College of Dentistry
Section of Orthodontics
305 W. 12th Ave
Columbus, Ohio 43210-2357
614-292-9100

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of subject	_____ Signature of subject
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for subject (when applicable)	_____ Signature of person authorized to consent for subject (when applicable)
_____ Relationship to the subject	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM

Witness(es) - May be left blank if not required by the IRB

_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM
_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM

APPENDIX B: HIPPA AUTHORIZATION

<p>THE OHIO STATE UNIVERSITY AUTHORIZATION TO USE PERSONAL HEALTH INFORMATION IN RESEARCH</p>
--

<p>Title of the Study: A New Approach to Orthodontic Informed Consent</p>
--

<p>OSU Protocol Number: 2009H0153</p>
--

<p>Principal Investigator: Henry W. Fields, Jr.</p>
--

Subject Name _____

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University's Notice of Privacy Practices or the study before signing this form.

Initials/Date: _____

Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.
- Those who oversee the study will have access to your information, including:
 - Members and staff of the Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
 - The Office for Responsible Research Practices
 - University data safety monitoring committees
 - The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
 - The Food and Drug Administration
 - The Office for Human Research Protections
 - The National Institutes of Health
 - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- The research sponsor and companies owned or connected with the sponsor: Delta Dental Master's Thesis Grant

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date_____

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-1120

or

Manju Oommen
Clinic Administration
The Ohio State University College of Dentistry
305 W. 12th Avenue
Columbus, OH 43210-2357
614-292-3016

- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

If you have any questions relating to your privacy rights, please contact

Manju Oommen
Clinic Administration
The Ohio State University College of Dentistry
305 W. 12th Avenue
Columbus, OH 43210-2357
614-292-3016

If you have any questions relating to the research, please contact

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-1120

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Henry W. Fields, Jr. and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature _____
(Subject or Legally Authorized Representative)

Name _____
(Print name above)
(If legal representative, also print relationship to subject.)

Date _____ Time _____ AM / PM

APPENDIX C: PARENTAL PERMISSION

PARENTAL PERMISSION
Biomedical/Cancer

IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0

The Ohio State University Parental Permission For Child's Participation in Research

Study Title: A New Approach to Orthodontic Informed Consent

Principal Investigator: Henry W. Fields, Jr.

Sponsor: Delta Dental Master's Thesis Grant

- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.
 - **Your child's participation is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.
 - **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
 - **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.
- 1. Why is this study being done?**

We would like to know how well we are communicating with our patients and their parents during our consultation appointment and improve this if needed.
 - 2. How many people will take part in this study?**

We hope to have 160 people in this study.

3. What will happen if my child takes part in this study?

You and your child will be randomly assigned (by chance) to one of two research study groups. Your child will have their normally scheduled consultation appointment with his/her orthodontic resident. The resident will review all the information about your child's orthodontic problem and how to best treat it. Your child may be asked to review the informed consent document and will watch a short informational slide show. Your child will be asked to complete a questionnaire and then interviewed on what the resident discussed with you. The both of you will also be asked to read a list of words that may or may not be familiar to you. We will also ask questions about how you are feeling, such as if you are feeling relaxed or worried.

4. How long will my child be in the study?

The study will take approximately 45-60 minutes.

5. Can my child stop being in the study?

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child expect from being in the study?

There are no anticipated risks, side effects or discomforts from being in the study.

7. What benefits can my child expect from being in the study?

Your child will not benefit directly from participating in the study. The study may benefit others in the future.

8. What other choices does my child have if he/she does not take part in the study?

You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my child's study-related information be kept private?

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law. Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your child's protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

10. What are the costs of taking part in this study?

Participating in this study may make your appointment longer than normal.

11. Will I or my child be paid for taking part in this study?

Your child will be given a \$15 gift certificate.

By law, payments to subjects are considered taxable income.

12. What happens if my child is injured because he/she took part in this study?

If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

125 You and your child will be provided with any new information that develops during the
126 course of the research that may affect your decision whether or not to continue
127 participation in the study.

128
129 You or your child may refuse to participate in this study without penalty or loss of
130 benefits to which you are otherwise entitled.

131
132 An Institutional Review Board responsible for human subjects research at The Ohio State
133 University reviewed this research project and found it to be acceptable, according to
134 applicable state and federal regulations and University policies designed to protect the
135 rights and welfare of participants in research.

136
137

138 **14. Who can answer my questions about the study?**

139
140

141 For questions, concerns, or complaints about the study you may contact Dr. Henry Fields or
142 Dr. Kelly Carr.

143

144 Henry Fields
145 The Ohio State University College of Dentistry
146 Section of Orthodontics
147 4088 F Postle Hall
148 305 W. 12th Ave.
149 Columbus, Ohio 43210-2357
150 614-292-1120

151

152 Kelly Carr
153 The Ohio State University College of Dentistry
154 Section of Orthodontics
155 305 W. 12th Ave.
156 Columbus, Ohio 43210-2357
157 614-292-9100

158

159

160 For questions about your child's rights as a participant in this study or to discuss other
161 study-related concerns or complaints with someone who is not part of the research team,
162 you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at
163 1-800-678-6251.

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PARENTAL PERMISSION
Biomedical/Cancer

IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0

169 If your child is injured as a result of participating in this study or for questions about a study-
170 related injury, you may contact Dr. Henry Fields or Dr. Kelly Carr.

171
172 Henry Fields
173 The Ohio State University College of Dentistry
174 Section of Orthodontics
175 4088 F Postle Hall
176 305 W. 12th Ave.
177 Columbus, Ohio 43210-2357
178 614-292-1120

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180 Kelly Carr
181 The Ohio State University College of Dentistry
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**PARENTAL PERMISSION
Biomedical/Cancer**

**IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0**

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

Relationship to the subject

Date and time AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time AM/PM

Witness(es) - May be left blank if not required by the IRB

Printed name of witness

Signature of witness

Date and time AM/PM

Printed name of witness

Signature of witness

Date and time AM/PM

APPENDIX D: ASSENT

ASSENT
Biomedical/Cancer

IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0

The Ohio State University Assent to Participate in Research

Study Title: A New Approach to Orthodontic Informed Consent
Researcher: Henry W. Fields, Jr.
Sponsor: Delta Dental Master's Thesis Grant

- You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.
- This form will tell you about the study to help you decide whether or not you want to participate.
- You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.
- It is okay to say "No" if you don't want to be in the study. If you say "Yes" you can change your mind and quit being in the study at any time without getting in trouble.
- If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.

1. What is this study about?

We want to know how much our patients understand about their orthodontic treatment.

2. What will I need to do if I am in this study?

You will be randomly assigned (by chance) to one of two research study groups. You will need to listen to the presentation by your orthodontic resident. The resident will explain what they plan to do to treat you. You may also read a few papers that talk about all the possible risks and your responsibilities when you are in treatment. We will also ask you to watch a short informational slide show and complete a questionnaire, read a list of words, and then interview you. In the interview we will ask you some questions about what you just heard and read. We will also ask questions about how you are feeling, such as if you are feeling relaxed or worried.

3. How long will I be in the study?

The study will take about 45-60 minutes of your time.

4. Can I stop being in the study?

You may stop being in the study at any time.

5. What bad things might happen to me if I am in the study?

There are no bad things that can happen if you are in the study.

6. What good things might happen to me if I am in the study?

There are no good things that can happen to you if you are in the study. It can help other people in the future because we can make our papers and presentations easier to understand.

7. Will I be given anything for being in this study?

You will be given a \$15 gift certificate for participating.

8. Who can I talk to about the study?

For questions about the study you may contact Dr. Henry Fields or Dr. Kelly Carr.

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave, PO Box 182357
Columbus, Ohio 43210-2357
614-292-1120

Kelly Carr
The Ohio State University College of Dentistry
Section of Orthodontics
305 W. 12th Ave, PO Box 182357
Columbus, Ohio 43210-2357
614-292-9100

To discuss other study-related questions with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

ASSENT
Biomedical/Cancer

IRB Protocol Number: 2009H0153
IRB Approval date: 8/14/09
Version: 1.0

Signing the assent form

I have read (or someone has read to me) this form. I have had a chance to ask questions before making up my mind. I want to be in this research study.

_____	_____	AM/PM
Signature or printed name of subject	Date and time	

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____	_____	
Printed name of person obtaining assent	Signature of person obtaining assent	
	_____	AM/PM
	Date and time	

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.

APPENDIX E: CUSTOMIZED SLIDESHOW ELEMENTS

Please ID at most 4 increased risk factors that you would highlight in the informed consent for this specific patient.

Patient Name:
Resident Name:

☐	Treatment time
☐	Health updates
☐	Tobacco product use
☐	Ceramic appliances and damage to enamel
☐	Accidental injury during adjustment appointments
☐	Wisdom teeth
☐	Impacted teeth and unerupted teeth
☐	Allergies to orthodontic appliances
☐	Large fillings and injured teeth that may need root canal therapy
☐	Extractions and orthognathic surgery for severe crowding and mismatched jaws
☐	Injury from braces and injury from headgear
☐	Abnormal jaw growth
☐	Temporomandibular Joint Disorders
☐	Tooth reshaping, interproximal reduction

APPENDIX F: SCRIPT FOR INVITATION TO PARTICIPATE

SCRIPT FOR INVITATION TO PARTICIPATE IN RESEARCH Measuring Informed Consent in Orthodontics

You and your child have been invited to voluntarily participate in a research study called “Measuring informed consent in Orthodontics.” This project is being conducted by me, Dr. Henry Fields, and colleagues in the Orthodontic section at The Ohio State University (room 4088F Postle Hall, 614-292-1120, or fields.31@osu.edu). This project will look at different ways of communicating informed consent information.

This project will involve things that would normally be done at the patient consultation/case discussion appointment such as reviewing the treatment planned for your child and discussing the benefits and risks of orthodontic treatment (informed consent). The additional tasks are to fill out a questionnaire and then go through an interview with me or a research assistant. Both you and your child will complete the questionnaires and be interviewed separately. The interview will be recorded. The research project will take approximately 45 minutes to an hour. There are no right or wrong answers. We are just interested in what you think.

The questions about your education, income, etc are optional. You can skip that part of the questionnaire if you wish.

We anticipate no discomforts or risks with participation.

You can choose not to participate in the study without penalty. You can also withdraw from the study at any time without penalty.

Your decision to participate or not participate will not affect your child’s treatment.

If you agree to participate, the orthodontic resident will explain your child’s treatment plan. You will then read the informed consent and view a short automatic slide presentation. The study will take place in a consultation room for privacy. The orthodontic resident will answer any questions you may have. You and your child will then be interviewed separately about the informed consent and treatment plan. This interview will be recorded. You and your child will also complete a questionnaire. A \$15 gift certificate will be given to your child for your time and participation.

If you have further questions, you can contact Dr. Fields in person in his office (4088F Postle Hall, OSU College of Dentistry), by telephone, or by email.

Thank you.

APPENDIX G: PARENTAL INTERVIEW SCRIPT

INTERVIEW SCRIPT FOR MAIN STUDY (SUBJECT-PARENT)

Script for main study interview (Subject – Parent)

This interview will help us find the best way to communicate with our patients and parents. This is not a test. There is no right or wrong answer. Your child's treatment will not be influenced by how you answer questions during this interview.

This part of the study will be tape recorded so the information can be analyzed later by the research investigators. Some of the questions may sound the same. Please answer each question as best as you can.

[Turn tape recorder on]

The research ID is [state the research ID].

[Informed Consent Questions]

1. What are the risks to the teeth and gums with braces on?
How can you prevent these things from happening?
2. What are the risks to the tooth roots during braces?
What could make it worse?
If the orthodontist notices some changes to the tooth roots what would the orthodontist do?
3. What are the risks to your child's teeth if ceramic braces are taken off?
4. When your child is done with braces, what does your child need to do to keep their teeth straight?
5. Some people have jaw pain or what they call "TMJ" or "TMD". How is this related to the braces or orthodontic treatment?
6. What problems can an injured tooth or a tooth that had a large cavity cause during braces?

7. What can you expect your child to feel after getting their braces on or having an adjustment on their braces?
Is there anything you can do about this?
8. What are some things that could happen while the orthodontist or assistant is working in your child's mouth with instruments?
9. When something comes loose in your child's mouth what should you do?
10. How do we fix mismatched jaws?
How do we fix crowded teeth?
11. Please name some of the things that can happen if your child's jaws do not grow as we expect or grow abnormally?
12. If there are teeth that are stuck in the jaws or fused to the bone, what can happen?
Can these teeth be pulled into the mouth?
13. How long is your child estimated to be in braces or have orthodontic treatment?
What are some things that could affect the treatment time?
Name some responsibilities you and your child have during treatment.
14. Braces may not be enough to perfectly fix your child's teeth. What else may need to be done to make them look right?
15. What are some important things your orthodontist needs to know about your child's health?
16. What is your orthodontist going to do about your child's wisdom teeth?
17. What would happen if your child developed an allergy to the materials in the braces?
18. What is your orthodontist's recommendation about smoking or using smokeless tobacco? Why?
- R19. Does your child have to wear anything after their braces are taken off?
What are their responsibilities?
How long do they have to wear it?
- R20. When your child comes in for an appointment, what does the orthodontist need to know about their health?
- R21. "TMJ" or "TMD" is associated with jaw pain. How does orthodontic treatment affect "TMJ" or "TMD"?

R22. Sometimes teeth are stuck or fused to the jaw bone and won't come into the mouth. What can be done about this and what are the risks?

Scenarios

I will now read to you a situation and ask you how you would handle the situation.

Amy got her braces a few days ago. Her mouth is sore especially when she is eating. What would you do?

Dr. Smith, your child's orthodontist, just showed you an x-ray of your child's teeth. She said that your child has root resorption of a few teeth in the upper jaw. What would you see?

You were checking your child's teeth to make sure he was brushing well and you noticed that his gums were bleeding. What is the reason for this and what would you do?

Your orthodontist just took Billy's braces off. There are white spots and circles on the front of each tooth that don't wipe off. What has happened and what can be done about this? What could have prevented this?

Your child has a tooth that needed to be pulled into the mouth. The tooth was being pulled into the mouth slowly, but all of a sudden it stopped moving. What could be the reason and what should be done about this?

Sara had her braces taken off 5 years ago. She is now 22 and her teeth do not fit together. In fact, her teeth don't come together at all when she closes her mouth. What happened?

Becky had a lot of cavities filled a year ago. The dentist told her that one cavity was really deep. She is now in braces and her teeth are sore. That one tooth is really throbbing. What could be happening to the tooth?

While eating dinner, your child finds a bracket loose in his mouth. What should you do?

Betsy was expected to be in braces for only 1 and a half years. It is now almost 2 years since she had her braces first put on. What could have happened?

John has two small teeth with spaces between them. He was told by his orthodontist that the spaces may not be closed. Why?

Jenny recently got her braces taken off and has retainers. She is wondering how long she is going to have to wear the retainers. What do you tell her?

Andrew has had braces for a year now and has been having some jaw soreness. He thinks the braces caused his jaw to be so sore. What would you say?

When Annie was 6, she tripped and chipped her front tooth. What might happen to that tooth now that she is getting braces?

Robert went to his doctor for a yearly check up. He has to take a new medication. Today he is going to his orthodontist for an adjustment appointment. What should he do at the appointment?

When someone has extremely crooked teeth or mismatched jaws what may need to be done?

[Turn off the tape recorder]

Administering the REALM[©]

Start on the left at the top and read down. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to skip to the next one.]

Administering the WRAT 3[©]

Start on the left at the top and read to the right. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to try anyway.]

[Ask the parent to complete the questionnaire.]

APPENDIX H: CHILD INTERVIEW SCRIPT

INTERVIEW SCRIPT FOR MAIN STUDY (SUBJECT-CHILD)

Script for Main study interview (Subject – Child)

This interview is a way for us to find the best method to communicate with and teach our patients and parents. This is not a test. There is no right or wrong answer. Your treatment will not be influenced by how you answer questions during this interview. This part of the study will be tape recorded so the information can be analyzed later by the research investigators. Some of the questions may sound similar. Please answer each every question as best as you can.

[Turn tape recorder on]

The research ID is [state the research ID].

[Informed Consent Questions]

1. What are the risks to the teeth and gums with braces on?
How can you prevent these things from happening?
2. What are the risks to the tooth roots during braces?
What could make it worse?
If the orthodontist notices some changes to the tooth roots what would the orthodontist do?
3. What are the risks to your teeth when ceramic braces are taken off?
4. When you are done with braces, what do you need to do to keep your teeth straight?
5. Some people have jaw pain or what they call “TMJ” or “TMD”. How is this related to the braces or orthodontic treatment?
6. What problems can an injured tooth or a tooth that had a large cavity cause during braces?
7. What can you expect to feel after getting your braces on or having an adjustment on your braces?
Is there anything you can do about this?

8. What are some things that could happen while the orthodontist or assistant is working in your mouth with instruments?
9. When something comes loose in your mouth what should you do?
10. How do we fix mismatched jaws?
How do we fix crowded teeth?
11. Please name some of the things that can happen if your jaws do not grow as we expect or grow abnormally?
12. If there are teeth that are stuck in the jaws or fused to the bone, what can happen?
Can these teeth be pulled into the mouth?
13. How long are you estimated to be in braces or have orthodontic treatment?
What are some things that could affect the treatment time?
Name some responsibilities you have during treatment.
14. Braces may not be enough to perfectly fix your teeth. What else may need to be done to make them look right?
15. What are some important things your orthodontist needs to know about your health?
16. What is your orthodontist going to do about your wisdom teeth?
17. What would happen if you developed an allergy to the materials in the braces?
18. What is your orthodontist's recommendation about smoking or using smokeless tobacco? Why?
- R19. Do you have to wear anything after your braces are taken off?
What are your responsibilities?
How long do you have to wear it?
- R20. When you come in for an appointment, what does the orthodontist need to know about your health?
- R21. "TMJ" or "TMD" is associated with jaw pain. How does orthodontic treatment affect "TMJ" or "TMD"?
- R22. Sometimes teeth are stuck or fused to the jaw bone and won't come into the mouth. What can be done about this and what are the risks?

Scenarios

I will now read to you a situation and ask you how you would handle the situation. Amy got her braces a few days ago. Her mouth is sore especially when she is eating. What would you do?

Dr. Smith, your orthodontist, just showed you an x-ray of your teeth. She said that you have root resorption of a few teeth in the upper jaw. What would you see on the x-ray?

You were checking your teeth to make sure you were brushing well and you noticed that your gums were bleeding. What is the reason for this and what would you do?

The orthodontist just took Billy's braces off. There are white spots and circles on the front of each tooth that don't wipe off. What has happened and what can be done about this? What could have prevented this?

You had a tooth that needed to be pulled into the mouth. The tooth was being pulled into the mouth slowly, but all of a sudden it stopped moving. What could be the reason it stopped moving? What should be done about this?

Sara had her braces taken off when she was 15 years old. She is now 22 and her teeth do not fit together. In fact, her teeth don't come together at all when she closes her mouth. What happened?

Becky had a lot of cavities filled a year ago. The dentist told her that one cavity was really deep. She is now in braces and her teeth are sore. That one tooth is really throbbing. What could be happening to the tooth?

While eating dinner, you find a bracket loose in your mouth. What should you do?

Betsy was expected to be in braces for only 1 and a half years. It is now almost 2 years since she had her braces first put on. What could have happened?

John has two small teeth with spaces between them. He was told by his orthodontist that the spaces may not be closed. Why?

Jenny recently got her braces taken off and has retainers. She is wondering how long she is going to have to wear the retainers. What do you tell her?

Andrew has had braces on for a year now and has been having some jaw soreness. He thinks the braces caused his jaw to be sore. What would you say?

When Annie was 6, she tripped and got a large chip on her permanent front tooth. She is now 14 and getting braces. What might happen to that tooth now that she is getting braces?

Robert went to his doctor for a yearly check up. He has to take a new medication. Today he is going to his orthodontist for an adjustment appointment. What should he do at the appointment?

When someone has extremely crooked teeth or mismatched jaws what may need to be done?

[Turn off the tape recorder]

Administering the REALM[®]

Start on the left at the top and read down. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to skip to the next one.]

Administering the WRAT 3[®]

Start on the left at the top and read to the right. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to try anyway.]

[Ask the child to complete the questionnaire.]

APPENDIX I: PARENTAL QUESTIONNAIRE
QUESTIONNAIRE FOR MAIN STUDY (SUBJECT-PARENT)

Parent/Guardian Questionnaire

Research ID _____ P _____ Date _____

1. What is your age in years and months? _____ Years _____ Months

Please circle the best answer for the following questions

2. What is your gender? Male Female

3. What was your total household income before taxes in the past year (including wages, social security, alimony, child support, and any other income)?

\$10,000 or less	\$50,000-\$74,999
\$10,001-\$24,999	\$75,000-\$99,999
\$25,000-\$49,999	\$100,000 or more

4. Who is living in your household? (check as many as you need to)

Single _____
With spouse or partner _____
With other adults: how many? _____
With own children: how many? _____
With parents: how many? _____
With children of spouse/partner/others': how many? _____

5. Have you ever had braces or orthodontic treatment?

Yes No

6. Are there other people in the household who have had braces or orthodontic treatment, or are currently in treatment?

Yes No

7. What is the highest grade of school or year of college that you finished?

8 th grade or less	2 years of college or technical school
9 th grade	Less than 4 years of college

4 year College graduate
Graduate school
Professional school (MD, DDS, JD, DO)

Working full time	Unemployed, looking for work
Working part time	Unemployed, not looking for work
Stay at home parent	Unable to work
Retired	Full or part time student

Yes No

Black, Hispanic
Black, Non-Hispanic
White, Hispanic
White, Non-Hispanic
South Asian
East Asian, Pacific Islander
Native American
Mixed

Black, Hispanic
Black, Non-Hispanic
White, Hispanic
White, Non-Hispanic
South Asian
East Asian, Pacific Islander
Native American
Mixed

Self-evaluation questionnaire (Y-6 item)

Research ID _____ Date _____

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you're feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Some what	Moderately	Very much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered *all* the questions.

APPENDIX J: CHILD QUESTIONNAIRE

QUESTIONNAIRE FOR MAIN STUDY (SUBJECT-CHILD)

Child Questionnaire

Research ID _____ C Date _____

1. What is your age in years and months? _____ Years _____ Months

Please circle the best answer for the following questions.

2. Are you male or female? Male Female

3. Have you had braces or orthodontic treatment?
Yes No

4. What grade of school are you in right now?

6th grade

7th grade

8th grade

9th grade

10th grade

11th grade

12th grade

GED

Technical School

College

Associate training

5. Do you have a part time job?

Yes

No

6. What is your job title? _____

7. Below is a line with a 0 on the left and 10 on the right. Please place a mark on the line that best describes how much **you** understand about the risks, benefits, and limitations of **your** orthodontic treatment.

Self-evaluation questionnaire (Y-6 item)

Research ID _____ Date _____

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you're feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Some what	Moderately	Very
much				
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered *all* the questions.